S. HRG. 98-1210

RADIATION CANCER LIABILITY

HEARING

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES UNITED STATES SENATE

NINETY-EIGHTH CONGRESS

SECOND SESSION

ON

EXAMINING HOW LIABILITY SHOULD BE ASSESSED FOR DAMAGES CAUSED BY LOW-LEVEL RADIATION EFFECTS WHICH APPEAR AS CANCER YEARS AFTER EXPOSURE

SEPTEMBER 18, 1984

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RADIATION CANCER LIABILITY

TUESDAY, SEPTEMBER 18, 1984

U.S. SENATE,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
Washington, DC.

The committee met, pursuant to notice, at 9:40 a.m., in room SD-430, Dirksen Senate Office Building, Senator Orrin G. Hatch (chairman of the committee) presiding.

Present: Senator Hatch.

OPENING STATEMENT OF SENATOR HATCH

The CHAIRMAN. We meet this morning to consider what progress has been made toward a serviceable solution to a puzzle that has stymied legislatures, agencies, and the courts. How should liability be assessed for damages for moderate to low-level radiation, an invisible agent whose occasional effects appear years after exposure as cancers that are indistinguishable from a plague of cancers caused by other things?

Solutions, especially when they are technical and possibly tenuous, rarely gain the notice that attends the problems themselves. Still, the true work of Government and science is the search for solutions. The two scientific committees represented on our first panel have been in serious pursuit of an answer to the problem just described, and therefore, their efforts warrant the attention of the Congress and the Nation.

Over the past 18 months, Dr. Rall's committee at the National Institutes of Health has been preparing the report and probability tables that are required by section 7(b) of the Orphan Drug Act. The promise of this project is a competent and intelligible appraisal of the causal connection between any dose of radiation and the cancer of any person who was exposed to this radiation prior to the onset of the disease. The hope is that the tables will bring coherence and fairness to the deliberations of persons who must judge whether radiation caused any particular cancer. The need is obvious since courts, workers compensation boards, and Federal agencies are befuddled by a bazaar of convoluted and conflicting testimonies. The public itself is confused. Plaintiffs do not know when to make claims, and defendants do not know when to contest them.

The use of radioepidemiology and probabilities to determine causality for radiogenic cancer claims was first proposed by me in October 1981 at a hearing that was devoted to resolving the special liability problem of those Americans who lived downwind of the Nevada nuclear testsites. The National Council for Radiation Protection and Measurement has recently established a committee to

show this radioepidemiological method. Dr. Victor Bond, who is chairman of this committee, testified at this hearing. Because of his testimony and the subsequent testimonies of other scientists, I sponsored legislation that requires the development and evaluation of the radioepidemiological method. Section 7(b) of the Orphan Drug Act resulted from this initiative.

My intention was to require the Department of Health and Human Services to attempt what the scientists at my hearings said could be done, and then to see and to let others see whether it is so. I did not and still do not endorse the method or the tables. But I am interested in the idea and hope others are interested also, because we need a reasonable means for measuring radiation liability. I have a wait-and-see attitude. This morning I have come to see.

Representatives of both the NIH committee and the original NCRP committee are present. Neither committee has published its report, but I understand that both reports should be ready soon. Since both committees are near the end of their task, it is appropriate to ask them what they think of the radioepidemiological method and their own efforts.

The task could not be easy. The time allowed was short, considering the work to be done. The data are massive, yet they are not sufficient for certainty and controversy attends their interpretation. As the witnesses know, I have had regular reports on the progress of both committees, and therefore, I know that both committees have worked long and hard and have faced serious obstacles.

I have been told repeatedly over the last 3 years that the radioepidemiological method is the best available for determining whether radiation is an improbable, possible, or probable cause of a cancer. This hearing will primarily address two further questions: (1) Even if the radioepidemiological method is the best, is it good enough? and (2) can this method be formulated in a format that will provide our people with a readily understandable standard for judging radiogenic cancer claims?

Before we turn to our witnesses, I must turn briefly to another matter involving radiation, to guidelines for the training and certification of radiation technicians who were mandated by the Omnibus Reconciliation Act of 1981 and that are being developed by the Department of Health and Human Services. Both Senator Randolph and I are concerned with the progress of this project also. We have arranged to submit interrogatories to Health and Human Services. Our questions and their answers, and perhaps some further written testimony on this subject, will be included in this hearing record without objection, and I would also include at this point a letter from Senator Jennings Randolph, dated September 18, 1984, to me.

[Material supplied follows:]

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United States Senate
COMMITTEE ON LABOR AND HUMAN RESOURCES
WASHINGTON, D.C. 20510

SEPTEMBER 18, 1984

HONORABLE ORRIN HATCH
CHAIRMAN
COMMITTEE ON LABOR AND HUMAN RESOURCES
UNITED STATES SENATE
WASHINGTON, D. C. 20510

DEAR MR. CHAIRMAN:

I DEEPLY APPRECIATE THE OPPORTUNITY YOU SO GRACIOUSLY AFFORDED ME TO SUBMIT A SERIES OF QUESTIONS TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICES DURING TODAY'S PUBLIC HEARING. AS YOU KNOW, IT WAS MY INTENTION TO BE PRESENT TODAY FOR THAT PURPOSE. UNFORTUNATELY, I COULD NOT IN GOOD CONSCIENCE CANCEL A LONG-STANDING EVENT, IN MY HONOR, REQUIRING ME TO TRAVEL TO A NEIGHBORING STATE THIS MORNING.

MR. CHAIRMAN, THE CONSUMER-PATIENT RADIATION HEALTH AND SAFETY ACT WAS ENACTED AS PART OF THE OMNIBUS BUDGET RECONCILIATION ACT OF 1981, PUBLIC LAW 97-35. THE ACT REQUIRED THE SECRETARY OF HEALTH AND HUMAN SERVICES TO PROMULGATE REGULATIONS ON MINIMUM FEDERAL STANDARDS FOR THE ACCREDITATION OF EDUCATIONAL PROGRAMS AND THE CREDENTIALING OF RADIOLOGIC PERSONNEL, AS WELL AS THE TRANSMITTAL OF A MODEL STATUTE FOR ADOPTION BY THE STATES, BY AUGUST 13, 1982. THREE YEARS HAVE ELAPSED SINCE ENACTMENT, AND STILL THE MINIMUM STANDARDS HAVE NOT BEEN PUBLISHED.

I KNOW THAT YOU UNDERSTAND AND SHARE MY CONCERN OVER THE FACT THAT 39 STATES DO NOTHING TO DETER THE USE OF UNTRAINED, INCOMPETENT INDIVIDUALS IN PERFORMING RADIOLOGIC PROCEDURES ON MEN, WOMEN AND CHILDREN IN THIS COUNTRY EVERY DAY -- 30 PERCENT OF WHOM ARE BEING OVER-EXPOSED TO UNNECESSARY AND HIGHLY DANGEROUS DOSES OF RADIATION. THE CONSEQUENCES OF OUR NOT TAKING ACTION NOW ARE TOO STAGGERING TO CONTEMPLATE.

ENCLOSED ARE A NUMBER OF QUESTIONS FOR SUBMISSION TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICES. WOULD YOU BE SO KIND AS TO REQUIRE THE DEPARTMENT'S RESPONSES BE APPROPRIATE AND TIMELY SO THAT THEY CAN BECOME PART OF TODAY'S OFFICIAL HEARING RECORD.

WITH SINCERE THANKS FOR YOUR ASSISTANCE IN THIS MATTER, I AM

TRULY,

Jennings

JENNINGS RANDOLPH

ENCLOSURE

QUESTIONS SUBMITTED BY SENATOR JENNINGS RANDOLPH, TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICES REGARDING THE STATUTORY REQUIREMENT TO PUBLISH MINIMUM STANDARDS TO PROTECT THE PUBLIC FROM POTENTIAL HAZARDS OF UNNECESSARY OVER-EXPOSURE TO MEDICAL/DENTAL RADIATION, UNDER PL 97-35, TITLE IX, KNOWN AS THE "CONSUMER-PATIENT RADIATION HEALTH & SAFETY ACT OF 1981." SUBMITTED ON TUESDAY, SEPTEMBER 18, 1984.

1. The Consumer-Patient Radiation Health and Safety Act of 1981, enacted August 13, 1981, (P.L. 97-35) Section 979 (a) provides as follows:

PROMULGATION OF STANDARDS

42 USC 10004.

Sec. 979. (a) Within twelve months after the date of enactment of this Act, the Secretary, in consultation with the Radiation Policy Council, the Administrator of Veterans' Affairs, the Administrator of the Environmental Protection Agency, appropriate agencies of the States, and appropriate professional organizations, shall by regulation promulgate minimum standards for the accreditation of educational programs to train individuals to perform radiologic procedures. Such standards shall distinguish between programs for the education of (1) medical radiologic technologists (including radiographers), (2) dental auxiliaries (including dental hygienists and assistants), (3) radiation therapy technologists, (4) nuclear medicine technologists, and (5) such other kinds of health auxiliaries who administer radiologic procedures as the Secretary determines appropriate. Such standards shall not be applicable to educational programs for practitioners.

(b) Within twelve months after the date of enactment of this Act, the Secretary, in consultation with the Radiation Policy Council, the Administrator of Veterans' Affairs, the Administrator of the Environmental Protection Agency, interested agencies of the States, and appropriate professional organizations, shall by regulation promulgate minimum standards for the certification of persons who administer radiologic procedures. Such standards shall distinguish between certification of (1) medical radiologic technologists (including radiographers), (2) dental auxiliaries (including dental hygienists and assistants), (3) radiation therapy technologists, (4) nuclear medicine technologists, and (5) such other kinds of health auxiliaries who administer radiologic procedures as the Secretary determines appropriate. Such standards shall include minimum certification criteria for individuals with regard to accredited education, practical experience, successful passage of required examinations, and such other criteria as the Secretary shall deem necessary for the adequate qualification of individuals to administer radiologic procedures. Such standards shall not apply to practitioners.

Has the Secretary by regulation promulgated any minimum standards for the accreditation for educational programs to train individuals to perform radiologic procedures as required by statute?

2. Has the Secretary by regulation promulgated minimum standards for the certification of persons to administer radiologic procedures as required by statute?

3. If no regulations have been promulgated please explain fully why the Secretary has ignored the requirements of this statute and also indicate when the Secretary will comply.

4. The Consumer-Patient Radiation Health and Safety Act of 1981, enacted August 13, 1981, (P.L. 97-35) Section 980 provides as follows:

MODEL STATUTE

Sec. 980. In order to encourage the administration of accreditation and certification programs by the States, the Secretary shall prepare and transmit to the States a model statute for radiologic procedure safety. Such model statute shall provide that—

(1) it shall be unlawful in a State for individuals to perform radiologic procedures unless such individuals are certified by the State to perform such procedures; and

(2) any educational requirements for certification of individuals to perform radiologic procedures shall be limited to educational programs accredited by the State.

Has the Secretary prepared and transmitted to the States a model statute for radiologic procedure safety as required by statute?

5. If model statute has been not transmitted to the States please explain fully why the Secretary has ignored the requirements of this section and also indicate when the Secretary will comply.

6. The Consumer-Patient Radiation Health and Safety Act of 1981, enacted August 13, 1981, (P.L. 97-35) Section 981 provides as follows:

COMPLIANCE

Sec. 981. (a) The Secretary shall take all actions consistent with law to effectuate the purposes of this subtitle.

(b) A State may utilize an accreditation or certification program administered by a private entity if—

(1) such State delegates the administration of the State accreditation or certification program to such private entity;

(2) such program is approved by the State; and

(3) such program is consistent with the minimum Federal standards promulgated under this subtitle for such program.

(c) Absent compliance by the States with the provisions of this subtitle within three years after the date of enactment of this Act, the Secretary shall report to the Congress recommendations for legislative changes considered necessary to assure the States' compliance with this subtitle.

(d) The Secretary shall be responsible for continued monitoring of compliance by the States with the applicable provisions of this subtitle and shall report to the Senate and the House of Representatives by January 1, 1982, and January 1 of each succeeding year the status of the States' compliance with the purposes of this subtitle. Report to Congress.

(e) Notwithstanding any other provision of this section, in the case of a State which has, prior to the effective date of standards and guidelines promulgated pursuant to this subtitle, established standards for the accreditation of educational programs and certification of radiologic technologists, such State shall be deemed to be in compliance with the conditions of this section unless the Secretary determines, after notice and hearing, that such State standards do not meet the minimum standards prescribed by the Secretary or are inconsistent with the purposes of this subtitle.

6. Please submit for the record copies of all reports submitted to the Senate and the House of Representatives on January 1, 1982, and January 1 of each succeeding year relating to the status of the States' compliance with the subtitle as required by statute.

7. Please submit for the record the step by step procedures required in connection with the preparation and issuance of regulations by the Secretary of the type required by P. L. 97-35 mentioned above.

* 8. DOES THE DEPARTMENT CONTEMPLATE, IN FUTURE PROMULGATION OF MINIMUM STANDARDS, TO APPLY THE BURDEN OF COMPLIANCE EQUALLY TO FEDERAL AGENCIES AND THE ARMED SERVICES AS WOULD BE APPLIED ON OTHER AFFECTED ENTITIES? OR DOES THE DEPARTMENT INTEND TO EXEMPT CERTAIN PERSONNEL? IF SO, WHAT IS THE JUSTIFICATION FOR DOING SO?

* 9. IF FINAL REGULATIONS/ MINIMUM STANDARDS NOW BEING CONSIDERED BY THE DEPARTMENT DO EXEMPT ARMED SERVICES PERSONNEL FROM COMPLYING WITH MINIMUM STANDARDS OF SAFETY IN PERFORMING RADIATION PROCEDURES (X-RAY) ON MEMBERS OF THE ARMED SERVICES AND THEIR DEPENDENTS IN ORDER TO SAVE MONEY, PLEASE JUSTIFY PLACING SUCH INDIVIDUALS AT RISK FROM DANGEROUS OVER-EXPOSURE TO RADIATION.

* 10. IS THE DEPARTMENT CONSIDERING EXEMPTING THE ARMED SERVICES FROM COMPLIANCE WITH MINIMUM SAFETY STANDARDS BECAUSE OF RECRUITMENT PROBLEMS? IF SO, EXPLAIN.

* 11. IT IS UNDERSTOOD THAT THE DEPARTMENT BELIEVES THERE IS LITTLE SUPPORT FOR THE EXISTING LEGISLATION BECAUSE OF A "LACK OF RESPONSE FROM MEMBERS OF CONGRESS TO THE DEPARTMENT'S NOTICE OF PROPOSED RULEMAKING."

DID IT OCCUR TO THE DEPARTMENT THAT A LACK OF RESPONSE TO THE NPRM MIGHT HAVE BEEN A SIGNAL THAT HAVING GIVEN THE DEPARTMENT THE AUTHORITY TO PUBLISH MINIMUM STANDARDS, THE CONGRESS HAD EVERY REASON TO EXPECT THAT IT WOULD DO SO WITHOUT FURTHER COMMENT AS TO THE INTENT OF CONGRESS IN ENACTING THE LAW?

IF THE DEPARTMENT BELIEVED A LACK OF CONGRESSIONAL RESPONSES TO THE NPRM INDICATED LITTLE SUPPORT FOR THE LEGISLATION, WHY DID THE DEPARTMENT NOT SEEK FURTHER CLARIFICATION OF CONGRESSIONAL INTENT IN THAT REGARD?

* 12. DOES THE DEPARTMENT BELIEVE THE "STATUTORY MANDATE" CANNOT BE ACCOMMODATED WITHOUT CREATING INSURMOUNTABLE PROBLEMS? IF SO, WHY? WHAT ARE THOSE "INSURMOUNTABLE PROBLEMS?"

13. HOW MANY STATES HAD MINIMUM HEALTH AND SAFETY STANDARDS ON THEIR BOOKS AT THE TIME OF ENACTMENT OF THE CONSUMER-PATIENT RADIATION HEALTH AND SAFETY ACT? HOW MANY HAVE PASSED SUCH LAWS SINCE ENACTMENT OF THE CONSUMER-PATIENT RADIATION HEALTH AND SAFETY ACT?

14. In 1966, the National Advisory Committee on Radiation reported to the Surgeon General that minimum Federal legal standards of education, training, and clinical experience for radiologists appeared to be necessary in order to bring about an increase in effective and safe ways in which such services could be delivered to the general public.

In 1967, HEW's Task Force on Environmental Health and Related Problems, concluded that radiation hazards, in spite of the amount of public sensitivity to the subject, were still in need of improvement in the area of safety controls, and that clearly more protections were needed for persons receiving radiologic treatments and services. It recommended that "ALL PERSONS USING X-RAY EQUIPMENT SHOULD BE LICENSED TO DO SO, AFTER FULFILLING WRITTEN EXAMS AS TO THEIR COMPETENCY TO PERFORM RADIOLOGIC PROCEDURES."

In 1967, the Surgeon General's X-Ray Advisory Committee on Public Health, in a report entitled "Public Health Considerations in Medical Diagnostic Radiation (X-rays)," observed that prime consideration should be given to the total public health interest with regard to radiologic procedures then in use, and that the stage had been reached when MANDATORY (EMPHASIS ADDED) requirements for competency examinations, training and clinical experience of operators of X-ray equipment were appropriate.

Has the Department's personnel reviewed these previous reports to the Surgeon General in their contemplation of drafting the minimum standards to implement the Consumer-Patient Radiation Health and Safety Act of 1981?

Has the Department's personnel reviewed the Hearing Record on Congressional efforts to enact the Consumer-Patient Radiation Health and Safety Act of 1981 as part of their preparation in writing the minimum standards or model statute required by the Act?

If not, has something occurred over the past 18 years or so that has convinced the Department and/or the Surgeon General that the need for safety controls such as competency examinations for radiologists and accreditation of training programs no longer exists? Explain.

*Questions Numbered 8 through 12 based on HHS Internal Memorandum dated July 15, 1984 (Standards for the Accreditation of Education Programs for, and the Credentialing of, Radiologic Personnel -- 42 CFR Part 75); Memo of Non-concurrence in Final Regulations from Dr. Robert B. Hlems to William Quinlin, Executive Secretariat.

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

NOV 29 1984

The Honorable Orrin G. Hatch
Chairman
Committee on Labor and
Human Resources
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

Thank you for your letter concerning the implementation of the Consumer-Patient Radiation Health and Safety Act of 1981 (Public Law 97-35). As the enclosed answers to your 15 questions indicate, the Department has been working to ensure the issuance of standards as required by Public Law 97-35.

Since the passage of the Act, the Department has been working diligently to develop the required materials in concert with other Federal entities, the States, and the private sector. We feel that the extra time required for such coordinated efforts will pay large dividends in terms of the usefulness of these regulations to the States and in their implementation by Federal agencies.

As you know, any regulations I approve must be reviewed by the Office of Management and Budget, as provided by E. O. 12291. I expect to send rules to OMB in the near future, and hope that they can be published within 60 days.

As you requested, enclosed also are copies of the reports submitted to the Congress on the status of States' compliance as required by Public Law 97-35.

An identical letter is being sent to Senator Randolph.

Sincerely,

Margaret M. Heckler

Margaret M. Heckler
Secretary

Enclosures

Questions Submitted by Senator Jennings Randolph, to the Department of Health and Human Services to Ascertain Why the Department Has Failed to Comply With the Statutory Requirement to Publish Minimum Standards to Protect the Public From Potential Hazards of Unnecessary Over-Exposure to Medical/Dental Radiation, Under PL 97-35, Title IX, Known as the "Consumer-Patient Radiation Health & Safety Act of 1981." Submitted on Tuesday, September 18, 1984.

1. The Consumer-Patient Radiation Health and Safety Act of 1981, enacted August 13, 1981, (P.L. 97-35) Section 979 (a) provides as follows:

Promulgation of Standards

Sec. 979. (a) Within twelve months after the date of enactment of this Act, the Secretary, in consultation with the Radiation Policy Council, the Administrator of Veterans' Affairs, the Administrator of the Environmental Protection Agency, appropriate agencies of the States, and appropriate professional organizations, shall by regulation promulgate minimum standards for the accreditation of educational programs to train individuals to perform radiologic procedures. Such standards shall distinguish between programs for the education of (1) medical radiologic technologists (including radiographers), (2) dental auxiliaries (including dental hygienists and assistants), (3) radiation therapy technologists, (4) nuclear medicine technologists, and (5) such other kinds of health auxiliaries who administer radiologic procedures as the Secretary determines appropriate. Such standards shall not be applicable to educational programs for practitioners.

(b) Within twelve months after the date of enactment of this Act, the Secretary, in consultation with the Radiation Policy Council, the Administrator of Veterans' Affairs, the Administrator of the Environmental Protection Agency, interested agencies of the States, and appropriate professional organizations, shall by regulation promulgate minimum standards for the certification of persons who administer radiologic procedures. Such standards shall distinguish between certification of (1) medical radiologic technologists (including radiographers), (2) dental auxiliaries (including dental hygienists and assistants), (3) radiation therapy technologists, (4) nuclear medicine technologists, and (5) such other kinds of health auxiliaries who administer radiologic procedures as the Secretary determines appropriate. Such standards shall include minimum certification criteria for individuals with regard to accredited education, practical experience, successful passage of required examinations, and such

other criteria as the Secretary shall deem necessary for the adequate qualification of individuals to administer radiologic procedures. Such standards shall not apply to practitioners.

Has the Secretary by regulation promulgated any minimum standards for the accreditation for educational programs to train individuals to perform radiologic procedures as required by statute?

RESPONSE: On July 12, 1983, the Department published a Notice of Proposed Rulemaking (NPRM) in the Federal Register which provided minimum standards for the accreditation of educational programs to train individuals to perform radiologic procedures. Public comments were received and appropriate changes made in the regulation. The Final Rule that will be published in the Federal Register is now under final review within the Department and will be forwarded to OMB for review under Executive Order 12291.

2. Has the Secretary by regulation promulgated minimum standards for the certification of persons to administer radiologic procedures as required by statute?

RESPONSE: The information provided in answer to question one also applies to the certification (licensure) standards, which were also included in the July 12, 1983 NPRM.

3. If no regulations have been promulgated please explain fully why the Secretary has ignored the requirements of this statute and also indicate when the Secretary will comply.

RESPONSE: The Department has not ignored the requirements of the statute. Since the enactment of the legislation, the Department has worked diligently to develop the required regulation. This process necessitated consulting with professional associations, accrediting bodies, certifying organizations, and State regulatory agencies. Many issues were raised by these organizations which required an enormous amount of staff time to resolve. However, by involving the States and the private sector in this time-consuming process, we believe the final regulations will have been improved.

4. The Consumer-Patient Radiation Health and Safety Act of 1981, enacted August 13, 1981, (P.L. 97-35) Section 980 provides as follows:

Model Statute

> Sec. 980. In order to encourage the administration of accreditation and certification programs by the States, the Secretary shall prepare and transmit to the States a model statute for radiologic procedure safety. Such model statute shall provide that--
>
> (1) it shall be unlawful in a State for individuals to perform radiologic procedures unless such individuals are certified by the State to perform such procedures; and
>
> (2) any educational requirements for certification of individuals to perform radiologic procedures shall be limited to educational programs accredited by the State.

Has the Secretary prepared and transmitted to the States a model statute for radiologic procedure safety as required by statute?

RESPONSE: A model statute has been developed by the Public Health Service (PHS) for transmittal to the States and is under final review in the Department. Because definitions and other wording in the model statute must be consistent with the standards, it was felt that the standards should be issued in the Federal Register prior to transmitting the model statute to the States.

5. If model statute has been not transmitted to the States please explain fully why the Secretary has ignored the requirements of this section and also indicate when the Secretary will comply.

RESPONSE: The requirements of the statute have not been ignored. Several drafts of a model statute have been prepared. This followed extensive review of existing State laws and model statutes and consultation with the States and professional associations. The drafts have been reviewed by many individuals and amended based upon their views. The model statute will be transmitted to the States shortly after the Final Rule on standards is published in the Federal Register.

6. The Consumer-Patient Radiation Health and Safety Act of 1981, enacted August 13, 1981, (P.L. 97-35) Section 981 provides as follows:

Compliance

Sec. 981. (a) The Secretary shall take all actions consistent with law to effectuate the purposes of this subtitle.

(b) A State may utilize an accreditation program administered by a private entity if--

(1) such State delegates the administration of State accreditation or certification program to such private entity;

(2) such program is approved by the State; and

(3) such program is consistent with the minimum Federal standards promulgated under this subtitle for such program.

(c) Absent compliance by the States with the provisions of this subtitle within three years after the date of enactment of this Act, the Secretary shall report to the Congress recommendations for legislative changes considered necessary to assure the States' compliance with this subtitle.

(d) The Secretary shall be responsible for continued monitoring of compliance by the States with the applicable provisions of this subtitle and shall report to the Senate and the House of Representatives by January 1, 1982, and January 1 of each succeeding year the status of the States' compliance with the purposes of this subtitle.

(e) Notwithstanding any other provision of this section, in the case of a State which has, prior to the effective date of standards and guidelines promulgated pursuant to this subtitle, established standards for the accreditation of educational programs and certification of radiologic technologists, such State shall be deemed to be in compliance with the conditions of this section unless the Secretary determines, after notice and hearing, that such State standards do not meet the minimum standards prescribed by the Secretary or are inconsistent with the purposes of this subtitle.

Please submit for the record copies of all reports submitted to the Senate and the House of Representatives on January 1, 1982, and January 1 of each succeeding year relating to the status of the State's compliance with the subtitle as required by statute.

RESPONSE: Enclosed are copies of the reports.

7. Please submit for the record the step-by-step procedures required in connection with the preparation and issuance of regulations by the Secretary of the type required by PL 97-35 mentioned above.

RESPONSE: Typically, the procedure followed by the Department in connection with the preparation and issuance of regulations by the Secretary of the type required by P.L. 97-35 is as follows:

When a decision is made to issue a regulation in the Department, the operating level, in this case the Bureau of Health Professions, develops specifications or a draft regulation and submits it to the Office of General Counsel for verification of legal sufficiency. Once there is agreement on the content, the proposed regulation is reviewed at the Agency level, in this case by the Health Resources and Services Administration (HRSA). If the Agency Administrator approves the proposed document, it is then sent to the Assistant Secretary for Health. His staff reviews it for compliance with PHS policy. Other PHS agencies that have an interest in the subject also receive copies for review and comment. After any PHS issues are resolved internally and with the initiating Agency and OGC, and the document revised to the satisfaction of the Assistant Secretary for Health, he signs the proposed regulation and sends it to the Office of the Secretary.

The proposed regulation is then examined by staff in the Office of the Secretary. Comments are obtained from key staff offices within the Department that may have a policy or operational interest in the regulation. Any issues that are identified are resolved, insofar as possible. If agreement is reached the regulation is submitted to the

Secretary for review. If any issues require her personal attention, they are resolved at that time. Once the Secretary approves the proposed regulation, it is submitted to the Office of Management and Budget (OMB) for review under the provisions of Executive Order 12291. After OMB review is completed, the regulation is sent to the Office of the Federal Register for publication, usually as a Notice of Proposed Rulemaking, with a specific period for public comment. After the close of the public comment period, the Department analyzes all responses received and prepares the Final Rule. The preamble of the Final Rule includes Department discussion of acceptance or rejection of all public comments. The process for Department review of the proposed Final Rule is similar to that for an NPRM.

The Health Resources and Services Administration of the Public Health Service undertook the following procedures with respect to the preparation and issuance of the regulation as required under Section 979. The procedures followed are presented below in outline form in their chronological sequence.

I. Three professional staff members of HRSA traveled to Chicago to consult with accrediting agencies, certifying bodies, and professional organizations

which would be directly involved and affected by the implementation of the Act.

II. A workshop with representation from each of the affected occupations was held in Arlington, VA, at which all interested organizations and individuals were invited to make presentations and/or submit written comments.

III. A Federal working group, comprised of representatives from the Department of Defense, National Institutes of Health, Environmental Protection Agency, Office of Personnel Management, Indian Health Service, Food and Drug Administration, and the Veterans Administration (VA), was formed to provide consultation.

IV. State agencies were contacted for their comments on the implementation of the Act.

V. A continuous dialogue was maintained with professional, accrediting and certifying agencies such as the American Registry of Radiological Technology, the American Society of Radiology Technology, nuclear medicine societies, and dental organizations. The comments and issues raised by these agencies were reviewed, analyzed, and taken into consideration in developing the standards.

VI. The Notice of Proposed Rulemaking was issued inviting public comments. The maximum allowable time of 120 days was provided to ensure that all interested parties would have an opportunity to respond. In addition, copies of the NPRM were sent to State licensing boards, and professional, accrediting and certifying agencies to solicit their comments. Public comments raised a number of issues which required resolution before a final rule could be drafted.

The following questions are based on Dept. of HHS internal memorandum dated July 15, 1984, entitled Standards for the Accreditation of Education Programs for, and the Credentialing of Radiologic Personnel -- 42 CFR Part 75; Memo of Non-concurrence in Final Regulations, from Dr. Robert B. Helms to Mr. William Quinlin (sic), Executive Secretariat.

8. Would regulations intended to be promulgated by the Department apply equally as to the burden of compliance on Federal agencies and the Armed Services as on other affected entities?

RESPONSE: The regulation will apply equally to all departments and agencies of the Federal government except as provided for under Section 983 of P.L. 97-35. The issue of how to apply the regulations to Federal agencies is being reviewed in response to a comment on the NPRM that a Federal agency would have problems complying with all of the requirements in that NPRM. Any provision that might be added to the final rule to address this issue would be designed to assure that health and safety is adequately protected. State law and regulation often provide to State licensing boards the kind of flexibility that would be intended by any such provision.

9. Does the Department intend to exempt certain personnel? If so, what is the justification for such exemption?

RESPONSE: The Department has proposed standards for accreditation of educational programs and the credentialing of radiographers, radiation therapy technologists, nuclear medicine technologists, dental hygienists, and dental assistants. Those standards, in general, follow existing requirements already recognized and accepted by the Committee on Allied Health Education and Accreditation of the American Medical Association, the Commission on Dental Accreditation of the American Dental Association, and private certifying agencies.

When we published that NPRM, we determined that it was not appropriate to recommend radiologic standards for other types of health personnel who may administer radiation. The Public Health Service advises that a fuller and more satisfactory base of information is necessary on existing practices, standards in the private sector, and job knowledge requirements, particularly of those occupations whose personnel have not previously been held to rigorously developed formal standards regarding their qualifications and competency to apply radiation.

The vast majority of those who administer ionizing radiation, other than doctors of medicine, osteopathy, dentistry, podiatry, and chiropractic, who have statutory exemption, fall into the five occupations for which standards were promulgated in the NPRM. The Center for Devices and Radiologic Health has testified that non-credentialed radiographic personnel account for only 10 percent of the population dose of medical ionizing radiation.

States remain free to propose additional standards for other personnel (such as nurses, medical office assistants, etc.), as they see fit, and they may do so through whatever regulatory form they consider appropriate. For example, additional State regulation of nurses might be accomplished in an entirely different manner from medical office assistants, a group not now regulated in any State. We believe States are in the best position to make informed decisions regarding the need for additional requirements and the manner in which this should be accomplished. We have in no way precluded additional State action, since any standards, although published by regulation as required by the Act, are merely advisory to States. Exclusive of licensed professionals exempted by statute

from coverage by these standards, the five occupational groups covered by the NPRM (other than licensed doctors of medicine, osteopathy, dentistry, podiatry, or chiropractic) administer the vast majority of ionizing radiation to patients.

10. If the Armed Services are exempted by Department regulations, please justify placing members of the Armed Services and their families at risk from over-exposure to radiation.

RESPONSE: The Armed Forces are not exempt from the standards as written. Personnel utilized by the services in the five occupations covered by the standards would be required to comply.

11. If VA hospitals are exempted from compliance with Department regulations on minimum safety standards, please justify placing veterans at risk from over-exposure to radiation in the diagnosis and treatment of such individuals.

RESPONSE: The VA is not exempt from the standards as written. Section 983 of the Act provides that the Veterans' Administration "shall, to the maximum extent feasible" prescribe regulations making these standards applicable in its facilities.

12. If the Department is considering exempting the Armed Services, VA hospitals, and the like, from compliance requirements under regulations it may publish, is that consideration based on claims by those entities that they would incur recruitment problems? That it would cost too much money to pay well-trained individuals with appropriate credentials certifying their competency to perform radiologic procedures?

RESPONSE: The Department is not exempting the Armed Services or the Veterans Administration or others from compliance with these standards. However, retention and recruitment problems associated with the NPRM have been raised by the Armed Services and the VA. A major issue raised is that many employees do not meet every requirement in the NPRM, and that the on-the-job experience of employees who do not meet certain formal requirements has enabled them to perform radiologic procedures without jeopardizing health and safety. The Department recognizes that implementation of formal standards proposed in the NPRM may be costly, and we are considering ways to address the issues raised by the comments in the final regulation, while maintaining needed health and safety protections.

13. According to the Internal Memorandum cited above, the Department believes that lack of responses from Members of Congress to its Notice of Proposed Rule Making is an indication that there is little support for the legislation. Please explain what the Department believes the intent of Congress was in enacting the legislation, if it did not intend that regulations be published? Did the Department make any effort to further ascertain the intent of Congress if it believed there was no need for it to comply with the law because of a lack of Congressional response to the NPRM?

RESPONSE: The internal memorandum that you have cited was an expression of specific concerns of the Acting Assistant Secretary for Planning and Evaluation elicited during the

review process within the Department. In subsequent discussions with the Assistant Secretary for Health, this matter has been resolved. The Department intends to comply with the intent of the Congress and publish the required regulations.

14. According to the Internal Memorandum cited above, the Department believes it cannot accommodate the "statutory mandate" without creating insurmountable problems. Please explain.

RESPONSE: The staff memo cited above has assisted the Department by articulating some very real problems with developing regulations implementing the statute. However, it does not represent the position of the Department since no final decision has been reached. The memo did not assert that there are insurmountable problems with implementing the statute. It did assert that there are a number of serious problems, not all of which may be able to be resolved by any one regulatory approach.

15. The history of this legislation dates back more than a dozen years. It was prompted in part by the following reports to the Surgeon General:

HEW's TASK FORCE ON ENVIRONMENTAL HEALTH AND RELATED PROBLEMS, 1967, which found that "all persons using X-ray equipment should be licensed to do so, after fulfilling written exams as to their competency to perform radiologic procedures."

Surgeon General's X-ray Advisory Committee on Public Health, 1967 report entitled: "Public Health Considerations in Medical Diagnostic Radiation (X-rays)," finding that prime consideration should be given to the total public health interest with regard to radiologic procedures then in use, and that the stage had been reached when mandatory (emphasis added) requirements for competency examinations, training and clinical experience of operators of X-ray equipment were appropriate.

National Advisory Committee on Radiation report to the Surgeon General (1966), observing that minimum federal legal standards of education, training, and clinical experience for radiologists appeared to be necessary in order to bring about an increase in effective and safe ways in which such services could be delivered to the general public:

Has the situation improved so dramatically that, in the Department's view, there is no further truth in the above reports?

How many states required accredited education and training programs for such personnel, and competency testing for individuals performing radiologic procedures beginning in 1966, and how many now require such training and competency testing?

RESPONSE: Although complete information is not available, in 1966 few if any States regulated personnel who performed radiologic procedures (except dental hygienists who were licensed in all States). In 1984 all States still license dental hygienists, 15 States regulate radiographers, 27 States require dental assistants who make radiographs to complete specified training and/or an examination, 11 States license radiation therapy technologists, and 5 States license nuclear medicine technologists.

Clearly, therefore, the situation has not remained static since those reports were issued more than 15 years ago. It has indeed improved to the extent that State activity in this area has been effective in protecting the public.

COMPLIANCE WITH THE CONSUMER-PATIENT RADIATION HEALTH AND SAFETY ACT OF 1981: ANNUAL REPORT FOR 1983

Report to the Congress
Of the Secretary of Health and Human Services
As Required by Section 981(d)
Of the Consumer-Patient Radiation Health
And Safety Act of 1981

November 30, 1983

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Health Resources and Services Administration
Bureau of Health Professions

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COMPLIANCE WITH THE CONSUMER-PATIENT RADIATION HEALTH AND SAFETY ACT: ANNUAL REPORT FOR 1983

INTRODUCTION

This is the second report on State compliance with the Consumer-Patient Radiation Health and Safety Act of 1981, Title IX of Public Law 97-35. Section 981(d) of the Act requires the Secretary of Health and Human Services to report to the Congress each January 1 on State compliance with standards for the accreditation of educational programs that train radiologic personnel and the standards for the certification of persons who perform medical and dental radiologic procedures.

The standards for accreditation and certification, and the model statute for States which is also required by P.L. 97-35, are intended to encourage adoption of uniform standards by the States, while preserving traditional State responsibilities for control of education and regulation of the professions. The Act neither prescribes nor authorizes penalties to States[1] that do not comply with the standards published by the Department. Therefore, these standards are advisory for States. However, Section 981(c) states that in the absence of State compliance within 3 years, "the Secretary shall report to the Congress recommendations for legislative changes considered necessary to assure the States' compliance with this subtitle."

Accreditation and certification standards were issued by the Secretary as a Notice of Proposed Rulemaking on July 12, 1983, which includes standards for the five occupations specifically identified by the Act: radiographers, dental hygienists, dental assistants, radiation therapy technologists, and nuclear medicine technologists. These are the occupations responsible for the great majority of radiologic examinations and procedures, and they are occupations for which voluntary organizations have developed well-accepted standards based on careful occupational analysis. When the proposed rule becomes final, it will add a new Part 75 to Title 42 of the Code of Federal Regulations, entitled "Standards for the Accreditation of Educational Programs for and the Certification of Radiologic Personnel." The Act exempts "practitioners," defined as licensed doctors of medicine, osteopathy, dentistry, podiatry, or chiropractic, from the standards.

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[1] As specified by Section 978(7) of the Act, the term "State" means the several States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

In addition, work is continuing on preparation of the model statute. The Health Resources and Services Administration of the Public Health Service has been responsible for development of the standards and the model statute. Because the Department's proposed standards have only recently been published and the model statute has not been completed, States have not had an opportunity to consider related options for legislative and administrative action.

HEALTH PROFESSIONS CREDENTIALING IN RELATION TO THE ACT

The control of educational quality and the regulation of professional practice in the health professions depend on a complex series of working relationships among voluntary (nongovernmental) organizations, and between these private organizations and their governmental counterparts. The terms accreditation, certification, and licensure, as they are applied to health professions education and practice, have taken on meanings and usages that are commonly accepted by voluntary organizations, and reflected in governmental studies of accreditation and credentialing, particularly in reports of the Department of Health, Education, and Welfare in 1971, 1974, and 1977.

Accreditation is commonly defined as the process by which an agency or organization evaluates an educational institution or a program of study as meeting certain predetermined qualifications or standards of education or service. In education, it applies to entire institutions or to specific programs of study.

The degree to which State governments involve themselves in program accreditation is variable but rather limited. Commonly, State agencies accept the accreditation standards of the voluntary agencies or establish working relationships with those agencies to jointly survey educational programs. In general, in approving programs, State governments do not seek to specify what educators must teach in detail.

Certification and licensure refer to methods of regulating personnel. Certification is commonly defined as the process by which a nongovernmental agency or association grants recognition to an individual who has met certain predetermined qualifications specified by that agency or association.[2] Thus, certification is a voluntary and nongovernmental process, yet it can be an effective means of controlling the competency of personnel to the extent that standards are rigorously developed, closely related to actual knowledge, skills, and competencies necessary for performance on the job, and accepted by employers. Certification by voluntary organizations is common in the health professions and is widely accepted by employers in the occupations discussed in this report.

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[2]The Act refers to "certification" as a State function. While an occasional State may use the terms "certification" or "registration," the more commonly used term for a State authorization to practice is "licensure." When States truly "certify" personnel, they simply protect the use of a specific title but do not prohibit other individuals from working in the profession or occupation.

Licensure is commonly defined as the process by which an agency of government authorizes an individual to engage in a given occupation and use a specific title. The Federal Government does not license health professionals, since licensure of health personnel is a State prerogative.

REGULATION OF RADIOLOGIC PERSONNEL

A great range of individuals and occupations is in some way involved in the administration of radiation to patients, in the control and monitoring of radiologic equipment, or in the use and handling of radioactive materials in the health industry.

Physicians who specialize in some aspect of radiation use include radiologists, nuclear medicine physicians, radiotherapists, and clinical pathologists (particularly specialists in isotopic pathology). Other physicians and practitioners such as dentists, podiatrists, and chiropractors also carry out radiologic procedures.

A large number of professional and technical personnel administer radiologic procedures under the supervision of licensed practitioners. These include radiographers, dental hygienists, dental assistants, radiation therapy technologists, and nuclear medicine technologists. With the exception of dental auxiliaries, voluntary credentialing programs for these personnel are firmly established and widely accepted.[3]

RADIOGRAPHERS (MEDICAL RADIOLOGIC TECHNOLOGISTS)

Radiographers are professionals who perform or may be called upon to perform a comprehensive scope of diagnostic radiographic procedures employing equipment that emits ionizing radiation, and who are delegated or exercise responsibilities for the operation of radiation-generating equipment, the shielding of patient and staff from unnecessary radiation, the appropriate exposure of radiographs, or other procedures that to any significant extent contribute to the determination of the site or dosage of the ionizing radiation to which a patient is exposed.

As the term is commonly used, radiographers are distinguished from other individuals whose use of ionizing radiation is limited to a few specific body sites or to a limited set of standard procedures. They also are distinguished from personnel in other clinical specialties who occasionally may be called upon to assist in diagnostic radiology.

Certification

Two nongovernmental bodies presently certify radiographers: the American Registry of Radiologic Technologists and the American Registry of Clinical Radiologic Technologists.

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[3]Dental hygienists are licensed in all States. Voluntary certification exists for dental assistants, but only a small proportion of the work force is certified.

The larger of these — the American Registry of Radiologic Technologists (ARRT) -- reported 133,743 certificate holders nationwide in November 1982. The ARRT grants certificates in radiography to individuals who successfully complete an examination and who meet prescribed educational requirements. Although the exact figures are not available, more than three-quarters of the work force are certified.

In general, graduation from a formal educational program in radiography accredited by the American Medical Association's Committee on Allied Health Education and Accreditation (CAHEA) is required of candidates who wish to sit for the examination. However, ARRT reviews the qualifications, on a case-by-case basis, of other applicants whose education and experience meet or exceed those of graduates from CAHEA-accredited programs. ARRT is an independent organization with four trustees appointed by the American College of Radiology and four appointed by the American Society of Radiologic Technologists.

The other certifying body — the American Registry of Clinical Radiologic Technologists (ARCRT) -- reported 13,852 certificate holders in July 1983. ARCRT grants certificates to individuals who pass its examination and who meet prescribed combinations of education and experience. To sit for the examination, applicants must have graduated from a 24-month program in radiography accredited by CAHEA, or have completed an approved military program in radiography, or have passed a challenge examination[4] offered by ARCRT. The challenge examination is open to individuals who are trained on the job and who have the equivalent of 5 years of full-time clinical experience. The challenge examination was developed by ARCRT in 1978. In addition, ARCRT will certify individuals who hold current certificates issued by ARRT and individuals licensed in radiography by States with standards equivalent to those of ARCRT.

Accreditation

CAHEA accredits educational programs for radiographers and is recognized for this purpose by the U.S. Department of Education and the Council on Postsecondary Accreditation (COPA). Virtually all educational programs for radiographers are accredited. The American College of Radiology and the American Society of Radiologic Technologists cooperate with CAHEA in the accreditation process. These organizations collaborate in developing the Essentials and Guidelines for accredited programs and appoint members to the Joint Review Committee on Education in Radiologic Technology, which evaluates programs and recommends accreditation decisions to CAHEA. Accreditation is reviewed at least every 5 years, or more frequently if circumstances warrant.

State Regulation

Licensure. Thirteen States license radiographers, all of which specify both educational and examination requirements before a license to practice is issued. There has been no change in the last year in the number of States

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[4]ARCRT offers a challenge examination for individuals who do not have formal preparation in the field. Individuals who pass the challenge examination become eligible to take the certification examination.

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that license radiographers. Ten of these 13 States have contracted with ARRT to administer its examination as the State licensure examination. All of these will exempt ARRT certificate holders from State examination requirements. Four of these also will license individuals currently certified by ARCRT if certain conditions are met by the applicant.

Three States administer their own licensure examination. One of the three will also license ARRT certificate holders if the applicant has achieved at least a score of 70 percent on the radiation protection and radiologic procedure sections of the ARRT exam. Puerto Rico requires applicants who have met its educational requirements and passed its licensure examination to serve 1 year of public service before a license is granted.

Table 1 shows the requirements of the 13 States that now regulate radiographers. It appears that these States' standards are in most respects comparable and in some cases identical to the voluntary accreditation standards of the CAHEA and the voluntary certification standards of the ARRT. It is anticipated that compliance with the Department's accreditation and certification standards will not pose a problem for these 13 States.

In addition, Alaska, Delaware, Illinois, Iowa, Maine, Michigan, Minnesota, New Mexico, Rhode Island, and Tennessee have enabling legislation for the regulation of radiologic personnel.[5] Iowa and Rhode Island set training standards for personnel functioning as operators of diagnostic X-ray equipment but do not issue licenses. Delaware, Illinois, Minnesota, and New Mexico are currently drafting regulations. Tennessee, Michigan, and Alaska have very general statutes, and have no plans to develop regulations. Maine's law was passed in July 1983.

There was considerable activity during the 1983 legislative sessions. At least 15 States considered legislation. Three new laws were passed, 1 is pending, and 11 failed. Several States will introduce proposals again next year. At least five other States have task forces and study groups in progress. Of the 50 States plus Puerto Rico and the District of Columbia, about 15 neither have a licensure program nor are considering developing one. Even though there is activity, many State legislatures and executive agencies say they have not considered or completed action because the Department's standards were just recently published and because the model statute has not yet been transmitted to the States.

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[5]These States have statutes that authorize or could be cited as authority for programs to regulate radiologic personnel. They have not yet instituted licensure programs.

Table 1. State licensure requirements for radiographers, July 1983[1]

State	CAHEA/JRC Education program approval accepted	Other licensure requirements	
		Exam required	or Certificate accepted
Arizona	Yes	ARRT	ARCRT
California	No	State	ARRT with conditions
Florida	Yes	ARRT	ARRT, ARCRT
Hawaii	No	State	None
Indiana	Yes	ARRT	ARRT
Kentucky	Yes, with joint site visit	ARRT	ARRT, ARCRT with conditions
Montana	Yes	ARRT	None
New Jersey	Yes, with joint site visit[2]	ARRT	ARRT
New York	Yes, with joint site visit	ARRT	ARRT
Oregon	Yes	ARRT	ARRT, ARCRT with conditions
Vermont	Yes, with joint site visit	ARRT	ARRT with conditions
West Virginia	Yes, with joint site visit	ARRT	ARRT
Puerto Rico	No	State & 1 yr. service	None

NOTES: The following States have statutes that authorize or could be cited as authority for licensure programs, but have not yet instituted a licensure program: Alaska, Delaware, Illinois, Iowa, Maine, Michigan, Minnesota, New Mexico, Rhode Island, and Tennessee. No other States license radiographers.

[1]Information on acceptance of credentials from other States or on "grandfathering" provisions not shown.

[2]Planned for the future.

KEY:

ARRT American Registry of Radiologic Technologists
ARCRT American Registry of Clinical Radiography Technologists
CAHEA/JRC Committee on Allied Health Education and Accreditation/Joint Review Committee on Education in Radiologic Technology

SOURCE: Council of State Governments, 1983.

Accreditation. All States except California, Hawaii, and Puerto Rico accept graduation from a radiography program accredited by CAHEA as fulfillment of the State's educational requirements. Five States cooperate with CAHEA and the Joint Review Committee on Education in Radiologic Technology to approve educational programs (or plan to in the next year).

DENTAL HYGIENISTS

Dental hygienists are oral health clinicians and educators who help patients develop and maintain good oral health. They provide preventive and therapeutic services under the supervision of dentists. Specific responsibilities vary, depending on the law of the State in which the hygienist is employed, but in all States include exposing and processing radiographs for diagnostic purposes among other duties.

Accreditation

Accreditation of educational programs in dental hygiene is conducted by the Commission on Dental Accreditation of the American Dental Association, which is recognized for this purpose by the U.S. Department of Education and COPA. Graduation from an accredited dental hygiene program is required for eligibility to sit for the licensure examination in all States except Alabama. The accreditation standards of the Commission include standards for curricula and instruction in dental radiography. Virtually all dental hygiene educational programs are accredited.

The Commission is composed of 20 members, including a representative from the American Dental Hygienists' Association, representatives of other disciplines whose educational programs are accredited by the Commission, and public members. Reaccreditation is conducted on a 5-year review cycle and a 10-year site visit cycle.

State Regulation

Licensure. All States require dental hygienists to successfully complete State licensing examinations in order to practice their profession. While individual States set their own licensure requirements, all require written and clinical examinations.

All States except Alabama and Delaware accept satisfactory scores on the national board examination in dental hygiene as full or partial fulfillment of the State requirement for a written examination. Additional written tests are required in all States except California, Illinois, Iowa, Massachusetts, New Jersey, New York, Puerto Rico, Rhode Island, and Utah. These additional examinations vary among jurisdictions. Alabama and Delaware require all candidates for licensure to pass an examination offered by the State, rather than the National Board. Alabama also requires a radiation safety test, which is given at the time of the licensing examination, and which must be passed in order to obtain a license.

Review of existing standards indicates that compliance with the accreditation and certification standards published by the Department does not appear to pose a problem for any State.

The national board examination in dental hygiene is conducted by the Joint Commission on National Dental Examinations of the American Dental Association and has been administered since 1962. In 1981, exposure and processing of dental radiographs, including considerations of radiation hygiene and safety, accounted for 46 items or 13 percent of the test. The examination is criterion-referenced.

State clinical examinations for dental hygiene licensure candidates include demonstration of knowledge and skills in oral inspection, dental charting, periodontal measurement, oral prophylaxis, and radiography. The weighting of these sections varies among States, but on the average, 25 percent of the examination is devoted to dental radiography.

In 1974, under a contract with the Department, the American Dental Hygienists' Association began the development of a criterion-referenced clinical examination in dental hygiene. Dental radiography accounts for 25 percent of the examination score. This test is now being used by the Central Regional Dental Testing Service (which administers examinations for 11 States), the Southern Regional Testing Agency (4 States), the Western Regional Examining Association (4 States), and State dental boards in California, Texas, Hawaii, and North Carolina.

Accreditation. Except for Alabama, all States require candidates for licensure in dental hygiene to have graduated from a formal educational program accredited by the Commission on Dental Accreditation. Alabama accepts graduates of accredited programs as eligible for the licensure examination, but also permits preceptor training of dental hygienists in the offices of designated practicing dentists. On-the-job-trained dental hygienists who complete the preceptorship program are then eligible for the licensure examination. This preceptorship program requires 2 weeks of study at the University of Alabama; 12½ hours of dental radiography are included in the course.

DENTAL ASSISTANTS

Dental assistants provide a wide range of clinical and laboratory skills and functions that aid the dentist in the delivery of oral health care. While dental assistants are permitted to assume expanded functions in some States, there are considerable differences among States in the definition of these functions. However, in all States except the District of Columbia, exposure and processing of dental radiographs for diagnostic purposes may be delegated to dental assistants.

Certification

The Dental Assisting National Board provides a voluntary national mechanism for certifying dental assistants. The Board operates under requirements adopted by the American Dental Association and is a member of the National Commission for Health Certifying Agencies.[6] Individuals who have successfully completed an educational program in dental assisting accredited by the Commission on Dental Accreditation are eligible to sit for the certification examination. Since 1980, on-the-job-trained dental assistants have been allowed to take the national examination as part of a study to determine appropriate requirements and methods for certifying personnel trained on the job.

Accreditation

Educational programs in dental assisting are accredited by the Commission on Dental Accreditation, which includes a representative of the American Dental Assistants Association. Accreditation standards for dental assisting programs include standards for curricula and instruction in dental radiography. Reaccreditation is conducted on a 5-year review cycle and a 10-year site visit cycle. Some dental assisting programs located in proprietary schools and some military programs are not accredited by the Commission. Virtually all other educational programs in dental assisting are accredited.

State Regulation

Dental assistants are permitted to expose and process dental radiographs in all States except the District of Columbia. While no State terms its regulatory procedure "licensure," 23 require dental assistants to complete specified training and/or an examination before engaging in dental radiography under the supervision of a dentist. Sixteen of these 23 States award certificates or register dental assistants who have met their requirements in specified areas, including radiography. The remaining 27 States permit the practice of dental radiography by assistants, but have no training or examination requirements.

Training and Examinations. Of the 23 States that regulate the dental assistant's use of dental radiography, requirements vary considerably. Some require only a specified training course, others require only an examination, while still others require both training and examination.

Table 2 displays the considerable variety now existing among these State requirements. It can be anticipated that the problem faced by these States in complying with the accreditation and certification standards issued by the Department may vary accordingly.

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[6]The National Commission for Health Certifying Agencies is a voluntary organization whose purpose is to improve the reliability, validity, and fairness of credentialing policies, procedures, and standards among voluntary agencies that certify the competence of health personnel.

Training requirements vary from graduation from a State-approved course in expanded functions for dental assistants (13 States), to graduation from a State-approved course in dental radiography alone (6), to graduation from an educational program accredited by the Commission on Dental Accreditation (1). Oregon and Georgia accept on-the-job training and New Jersey has no training requirements. Georgia requires that the dental assistant be trained by the supervising dentist and Iowa requires that the dentist certify the assistant has demonstrated clinical proficiency in dental radiography, while under his supervision for at least one month.

Five States accept certification by the Dental Assisting National Board as fulfillment of their requirements. Six States will permit dental radiography by assistants who have passed State-administered written and clinical examinations, and 10 States use written examinations only. In some States, these examinations are conducted by State dental boards or dental associations, and in others, by radiation control agencies or environmental protection agencies. The content of training courses and examinations varies among States.

RADIATION THERAPY TECHNOLOGISTS

Radiation therapy technologists, working from a prescription and with a radiotherapist, are professionals who utilize equipment that generates ionizing radiation for therapeutic purposes on human subjects. Using X-ray equipment, radionuclides, and electron beam equipment, they expose specific areas of the body to prescribed doses of ionizing radiation, assist in tumor localization and dosimetric procedures, assist in the proper operation of controlling devices, and in radiation protection for patients and clinical personnel.

Certification

ARRT provides a voluntary national system for certification of radiation therapy technologists. ARRT awards certificates to individuals who successfully complete an examination and meet prescribed educational requirements.

In general, graduation from a formal educational program in radiation therapy technology accredited by CAHEA is required of candidates who wish to sit for the examination. However, ARRT reviews the qualifications, on a case-by-case basis, of other applicants whose education and experience meet or exceed those of graduates of CAHEA-accredited programs. ARRT reported 3,289 certificate holders in November 1982. Although the exact figures are not available, about two-thirds of the work force are certified.

Table 2. State training, examination, and credentialing requirements for dental assistants making dental radiographs, July 1983

State	Required training	Required examinations			Credential issued
		Dental Assisting National Board	State		
			Written	Clinical	
Arizona	Expanded function	No	Yes	Yes	Certificate
California	Expanded function	No	Yes	No	Certificate
Colorado	Approved course	No	No	No	None
Florida	Approved course	No	No	No	Registration
Georgia	By supervising dentist	No	No	No	None
Indiana	Approved course	No	Yes	No	Certificate
Iowa	Approved course	No	Yes	No[5]	Certificate
Kentucky	Expanded function	No	Yes	No	Certificate
Maryland	Expanded function[1]	Yes	Yes[1]	No	Registration
Michigan	Expanded function	No	Yes	Yes	None
Minnesota	Expanded function	No	Yes	No	Registration
Montana	Expanded function	No	Yes	Yes	None
Nebraska	Expanded function	No	No	No	None
New Hampshire	Expanded function	No	Yes	Yes	Certificate
New Jersey	None	Yes	Yes[1]	No	Registration
North Carolina	Expanded function	No	Yes	Yes	Certificate
North Dakota	Accredited program	Yes	No	No	None
Oklahoma	Expanded function	No	Yes	No	Certificate
Oregon	6 months on-the-job	No	Yes	Yes	Certificate
Rhode Island	Approved course	No	No	No	None
Tennessee	Expanded function	No	Yes	No	Registration
Vermont	Expanded function[1]	Yes	No	No	Registration[2]
Virginia	Approved course[3]	Yes[4]	Yes[1]	No	Certificate

NOTES: The District of Columbia does not permit dental assistants to make dental radiographs. The following States have statutes that authorize or could be cited as authority for licensure programs, but have not yet instituted a licensure program: Illinois, Maine, and New Mexico. All other States not listed above permit dental assistants to make dental radiographs without restriction.

[1]Not required if certified by the Dental Assisting National Board.

[2]Dental Assisting National Board certification accepted in lieu of State registration.

[3]State provides but does not require a home-study course in dental radiography.

[4]Accepted if applicant provides statement that he/she has completed training in dental radiography.

[5]Supervising dentist must certify the applicant's clinical proficiency.

KEY:

Certificate	Certified by a State agency
Registration	Registered by the State dental board
Expanded function	Expanded function training course
Approved course	Approved training course in dental radiography
Accredited program	Dental assisting program accredited by the Commission on Dental Accreditation

SOURCES: Commission on Dental Accreditation, Division of Educational Measurements, Legal Provisions for Delegating Expanded Functions to Dental Hygienists and Dental Assistants (Chicago: American Dental Association, January 1981).

Council of State Governments, 1983.

Accreditation

As is the case for educational programs for radiographers, educational programs for radiation therapy technologists are accredited by CAHEA, with the cooperation of the American College of Radiology, the American Society of Radiologic Technologists, and the Joint Review Committee on Education in Radiologic Technology. Accreditation is reviewed every 5 years, or more frequently if circumstances warrant. Virtually all programs in radiation therapy technology are accredited.

State Regulation

Licensure. Seven States license radiation therapy technologists. In addition, Hawaii and Florida allow radiologic technologists to perform both diagnostic and therapeutic procedures, although they do not license radiation therapy technologists as a separate occupational category. Of these seven States, five have contracted with ARRT to administer its examination as the State licensure examination. California and Puerto Rico administer their own examinations. Arizona will also accept the ARCRT certificate.

Table 3 displays the current status of State requirements. It does not appear that compliance with the accreditation and certification standards published by the Department will pose a problem for these seven States.

Enabling legislation exists in Alaska, Delaware, Illinois, Indiana, Iowa, Kentucky, Maine, Michigan, Minnesota, New Mexico, and Tennessee. At least four of the States are actively developing programs. Current activity by the States is more limited for radiation therapy technologists than for radiographers, although many of the States that are considering licensure of radiographers are also including radiation therapy technologists (see radiographer section).

Accreditation. Among the seven licensure States, all but California and Puerto Rico accept graduation from a CAHEA-accredited program. California also accepts training and experience other than formal education as a possible means of qualifying for the licensure examination. New York conducts joint site visits with CAHEA, and Vermont will begin to do so in the future.

NUCLEAR MEDICINE TECHNOLOGISTS

Nuclear medicine technologists are professionals who conduct *in vivo* or *in vitro* detection and measurement of radioactivity for medical purposes or who administer radiopharmaceuticals to human beings.

In vivo procedures involve the administration of radioactive tracer chemicals to the patient. In one type of procedure, the tracer is administered, and after a period of time instruments are employed to measure the radioactivity emitted from the body in the vicinity of the organ in question. To accomplish this, the tracer must emit gamma radiation powerful enough to affect recording devices, but because tracers have short half-lives, irradiation of patients' tissues continues only briefly after the recording has been completed. In another type of *in vivo* procedure, a tracer is administered to the patient,

Table 3. State licensure requirements for radiation therapy technologists, July 1983[1]

State	CAHEA/JRC educational program approval accepted	Other licensure requirements	
		Exam required	or Certificate accepted
Arizona	Yes (2 year programs)	ARRT	ARCRT
California[2]	No	State	ARRT with conditions
New Jersey	Yes	ARRT	ARRT with conditions
New York	Yes, with joint site visit	ARRT	ARRT
Oregon	Yes	ARRT	ARRT
Vermont	Yes, with joint site visit[3]	ARRT	ARRT
Puerto Rico	No	State & 1 yr. service	None

NOTES: Florida and Hawaii allow radiologic technologists to perform both diagnostic and therapeutic procedures, although they do not license radiation therapy technologists as a separate occupational category. The following States have statutes that authorize or could be cited as authority for licensure programs, but have not yet instituted a licensure program: Alaska, Delaware, Illinois, Indiana, Iowa, Kentucky, Maine, Michigan, Minnesota, New Mexico, and Tennessee. No other States license radiation therapy technologists.

[1]Information on acceptance of credentials from other States and on "grandfathering" provisions not shown.

[2]Also accepts training and experience in lieu of formal education.

[3]Planned for future.

KEY:

ARRT American Registry of Radiologic Technologists
CAHEA/JRC Committee on Allied Health Education and Accreditation/Joint Review Committee on Education in Radiologic Technology
ARCRT American Registry of Clinical Radiologic Technologists

SOURCE: Council of State Governments, 1983.

and after a specified period of time a sample of body tissue or fluid is removed, and the amount of tracer in the sample is measured. In vitro procedures do not require exposure of the patient to radioactive materials. In vitro tests are performed by clinical laboratory personnel as well as nuclear medicine technologists and clinical chemists.

Certification

Three non-governmental organizations currently certify nuclear medicine technologists. The Nuclear Medicine Technology Certification Board (NMTCB) reported 7,153 certificate holders as of September 1982, when the annual exam was given. NMTCB, which was formed in the mid-70's with encourgement from the Society of Nuclear Medicine and its technologist section, is an independent agency and is a member of the National Commission for Health Certifying Agencies.

The American Society of Clinical Pathology (ASCP) reported 1,895 certificate holders in February 1983. NMTCB and ASCP are in the process of signing a merger agreement. ASCP will probably give its last examination in August 1983.

ARRT, the oldest of the these bodies, reported 8,624 certificate holders as of November 1982. Their examinations are given three times a year. Since a large majority of individuals are certified by more than one organization, there are somewhat less than 10,000 certified nuclear medicine technologists. Although the exact figures are not available, more than three-quarters of the work force are certified.

All three organizations award certificates to individuals who have successfully completed an examination and meet prescribed educational requirements. In general, all three organizations require graduation from a CAHEA-accredited program, although alternative pathways exist to allow individuals with other prescribed combinations of training and experience to sit for the examination. Examinations offered by these agencies differ somewhat, and eligibility requirements for those individuals who have not graduated from accredited educational programs also differ.

Accreditation

Educational programs for nuclear medicine technologists are accredited by CAHEA. The American College of Radiology, the American Society of Medical Technology, the American Society of Clinical Pathologists, the American Society of Radiologic Technologists, and the Society of Nuclear Medicine cooperate with CAHEA in the accreditation process. The program review committee is the Joint Review Comittee on Educational Programs in Nuclear Medicine Technology, which includes four members of the Society of Nuclear Medicine (two physicians, two technologists) and two members from each of the other professional associations listed above. To maintain accreditation, programs are resurveyed once every 5 years, or more frequently if indicated. Virtually all educational programs for the profession are accredited.

State Regulation

Licensure. New Jersey, Vermont, and Puerto Rico license nuclear medicine technologists. New Jersey and Vermont have contracted with ARRT for the use of its examination, and Puerto Rico administers its own examination. The two States that contract with ARRT also will license individuals who hold current certificates from ARRT, NMTCB or ASCP. Puerto Rico requires 1 year of public service, beyond State-approved training and examination, before issuing a license.

It does not appear that compliance will pose a problem for these three States.

In addition, California, Delaware, Illinois, Minnesota, and New Mexico are developing licensure programs. Alaska, Kentucky, Maine, Michigan, and Tennessee also have enabling legislation. Georgia and Virginia have task forces working on the subject. Current activity by the States is more limited for nuclear medicine technologists than for radiographers, although some of the States that are considering licensure of radiographers are also including nuclear medicine technologists (see radiographer section).

Accreditation. Of the three States that license nuclear medicine technologists, Vermont and New Jersey accept graduation from a CAHEA-accredited program as fulfilling the eligibility requirement to take the licensure examination, while Puerto Rico reserves all standard-setting and program-approval authority to a designated State agency. Both Vermont and New Jersey conduct joint site visits with CAHEA/JRC when accrediting programs.

COMPLIANCE WITH THE CONSUMER-PATIENT RADIATION HEALTH AND SAFETY ACT OF 1981: ANNUAL REPORT FOR 1982

Report to the Congress
Of the Secretary of Health and Human Services
As Required by Section 981(d)
Of the Consumer-Patient Radiation Health
And Safety Act of 1981

April 22, 1983

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Health Resources and Services Administration
Bureau of Health Professions

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COMPLIANCE WITH THE CONSUMER-PATIENT RADIATION HEALTH AND SAFETY ACT: ANNUAL REPORT FOR 1982

INTRODUCTION

This is the first report on State compliance with the Consumer-Patient Radiation Health and Safety Act of 1981, Title IX of Public Law 97-35. Section 981(d) of the Act requires the Secretary of Health and Human Services to report to the Congress each January 1 on State compliance with standards for the accreditation of educational programs that train radiologic personnel and the standards for the certification of persons who perform medical and dental radiologic procedures. The text of the Act is provided in Appendix I.

For purposes of this report, the key provisions of the Act are contained in:

-- Section 979, which requires promulgation of standards,
-- Section 980, which requires issuance of a model statute, and
-- Section 981, which addresses State compliance.

ACCREDITATION AND CERTIFICATION STANDARDS

In order to protect the public from the potential hazards of unnecessary exposure to medical and dental radiation, section 979 of the Act requires the Secretary to issue standards for the accreditation of educational programs to train individuals to perform radiologic procedures and for the certification of such individuals. Specifically, the Act requires that accreditation and certification standards distinguish between:

-- Medical radiologic technologists (radiographers);
-- Dental auxiliaries (dental hygienists and dental assistants);
-- Radiation therapy technologists;
-- Nuclear medicine technologists; and
-- Such others kinds of health auxiliaries who administer radiologic procedures as the Secretary determines appropriate.

The Act exempts "practitioners," defined as licensed doctors of medicine, osteopathy, dentistry, podiatry, or chiropractic, from the standards to be issued. The Act requires that these standards be promulgated by regulation 1 year after the enactment of P.L. 97-35.

COMPLIANCE

The Act permits States[1] to utilize private accreditation or certification programs if: the State delegates administration of the program; the program is approved by the State; and the program is consistent with the standards issued by the Department.

The Act contains no penalties for States that do not comply. The standards for accreditation and certification, and the model statute, are intended to encourage adoption of uniform standards by the States, while preserving traditional State responsibilities for control of education and regulation of the professions. However, if States do not comply within 3 years, the Secretary is required to report to the Congress on recommendations for legislative changes considered necessary to assure State compliance.

CURRENT STATUS

Accreditation and certification standards were recently approved by the Secretary as a Notice of Proposed Rulemaking that would add a new Part 75 to Title 42 of the Code of Federal Regulations, entitled "Standards for the Accreditation of Educational Programs for and the Certification of Radiologic Personnel." This Notice of Proposed Rulemaking has been forwarded to the Office of Management and Budget for review. The Notice includes standards for radiographers, dental hygienists, dental assistants, radiation therapy technologists, and nuclear medicine technologists. In addition, work is nearing completion on preparation of a model statute. The Health Resources and Services Administration (HRSA) of the Public Health Service has been responsible for development of the standards and the model statute. Because the Department's standards have not yet been published, States have not had an opportunity to consider options for legislative and administrative action.

CONSULTATION AND DEVELOPMENT OF STANDARDS

Standards will be published for the five professional groups listed above. These groups are responsible for the great majority of examinations and patient exposures to ionizing radiation. They are also the professions for which voluntary agencies have undertaken considerable work to develop and refine accreditation and certification standards. These voluntary standards have wide acceptance in the professional community and among those State agencies that currently regulate radiologic personnel, and reflect the type of

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[1]As specified by Section 978(7) of the Act, the term "State" means the several States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands. Information was available for this report on the 50 States, the District of Columbia, and Puerto Rico.

concern for patient protection and safety that the Act is intended to foster. As a result, the standards promulgated by the Department follow these closely in many areas.

Because the Act required that the standards be developed in consultation with appropriate Federal agencies, including the Veterans Administration and the Environmental Protection Agency, a working group was formed to give official representatives of Federal agencies that employ these personnel the opportunity to provide information and comment during the development of standards.

Agencies of States, including licensing agencies, boards that regulate health occupations, health departments, and radiation control agencies, were contacted and invited to contribute information and advice, as were appropriate professional organizations, voluntary accrediting and certifying agencies in the affected occupations, and employers.

Draft standards were then circulated to these organizations as well as to individuals with an expressed interest. A 4-day workshop was held for all interested parties to make presentations and/or submit written comments. Approximately 350 agencies, organizations, and individuals were contacted during this process.

HEALTH PROFESSIONS CREDENTIALING IN RELATION TO THE ACT

The control of educational quality and the regulation of professional practice in the health professions depends on a complex series of working relationships among voluntary (nongovernmental) organizations, and between these private organizations and their governmental counterparts. The terms accreditation, certification, and licensure, as they are applied to health professions education and practice, have taken on meanings and usages that are commonly accepted by voluntary organizations, and reflected in governmental studies of accreditation and credentialing, particularly in reports of the Department of Health and Human Services in 1971, 1974, and 1977.

Accreditation is commonly defined as the process by which an agency or organization evaluates an educational institution or a program of study as meeting certain predetermined qualifications or standards of education or service. In education, it applies to entire institutions or to specific programs of study.

In health occupations, accreditation of educational programs in a specific discipline is quite different from any permission a State might give an institution to operate within the State. Accreditation of educational programs in a specific discipline, as opposed to institutional accreditation (which may be granted by a State agency or a regional body), has been a function of voluntary organizations that draw upon the expertise of professional associations and educators in relevant disciplines.

Voluntary accrediting agencies may seek recognition from the Council on Postsecondary Accreditation (COPA), a nongovernmental agency that reviews accrediting processes and promotes uniformity and fairness in accrediting. In addition, the U.S. Department of Education grants recognition to accrediting agencies that meet its standards. Many Federal programs that involve

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financial aid to institutions or educational programs in specific disciplines require that the institution or program be accredited by an agency recognized for this purpose by the Department of Education.

Voluntary accrediting agencies set standards for curricula, program administration, instructional staff, laboratories and facilities, due process for students, and the like, to insure educational quality. Accordingly, an agency such as the American Medical Association's Committee on Allied Health Education and Accreditation (CAHEA) will adopt Essentials, which are the criteria against which programs will be measured, and Guidelines, which incorporate detailed explanatory material that will aid the program (and the reviewers from the accrediting agency) in interpreting and meeting the standards in the Essentials. (The terminology of Essentials and Guidelines is specific to CAHEA, but the principle is common.)

The degree to which State governments involve themselves in program accreditation is variable, but rather limited. Commonly, State agencies accept the accreditation standards of the voluntary agencies, or establish working relationships with those agencies to jointly survey educational programs. In general, in approving programs, State governments do not seek to specify what educators must teach in detail.

Certification and licensure refer to methods of regulating personnel. Certification is commonly defined as the process by which a nongovernmental agency or association grants recognition to an individual who has met certain predetermined qualifications specified by that agency or association.[1] Thus, certification is a voluntary and nongovernmental process, yet it can be an effective means of controlling the competency of personnel to the extent that standards are rigorously developed, closely related to actual knowledge, skills, and competencies necessary for performance on the job, and accepted by employers. Certification by voluntary organizations is common in the health professions and is widely accepted by employers in the occupations discussed in this report.

Licensure is commonly defined as the process by which an agency of government authorizes an individual to engage in a given occupation and use a specific title. The Federal Government does not license health professionals, since licensure of health personnel is a State prerogative.

The development of a certification or licensure program that has been shown to be valid and reliable and that includes requirements for eligibility, educational preparation, experience (as necessary), and credentialing examinations is a costly and time-consuming effort. Thoroughness in undertaking to develop such a program is essential for a variety of reasons: to insure that the requirements established are closely related to the knowledge and competencies

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[1]The Act refers to "certification" as a State function. While an occasional State may use the terms "certification" or "registration," the more commonly used term for a State authorization to practice is "licensure." When States truly "certify" personnel, they simply protect the use of a specific title, but do not prohibit other individuals from working in the profession or occupation.

necessary to perform effectively; to insure that the requirements are an appropriate basis for granting or denying credentials to individuals; and to insure that the requirements will survive legal challenge by unsuccessful applicants on professional, procedural, or constitutional grounds.

Development of a suitable examination is often beyond the resources of a State or professional association. Because of this, HRSA has for some years assisted professional associations in various allied health and public health occupations in developing credentialing programs. This assistance has involved three phases.[1] Phase I, or role delineation, involves identification, refinement, and verification of the competencies necessary for practice. It may lead to development of curriculum resource guides for educational programs, self-assessment instruments for practitioners, and continuing competency materials. Phase II involves the development of criterion-referenced[2] credentialing examinations that are designed to test the competencies identified in the role delineation. Phase III is examination administration. HRSA has supported Phases I and II and encouraged professional associations and States to utilize these materials.

REGULATION OF RADIOLOGIC PERSONNEL

A great range of individuals and occupations is in some way involved in the administration of radiation to patients, in the control and monitoring of radiologic equipment, or in the use and handling of radioactive materials in the health industry.

Physicians who specialize in some aspect of radiation use include radiologists, nuclear medicine physicians, radiotherapists, and clinical pathologists (particularly specialists in isotopic pathology). Other physicians and practitioners such as dentists, podiatrists, and chiropractors also carry out radiologic procedures.

A large number of professional and technical personnel administer radiologic procedures under the supervision of licensed practitioners. These include radiographers, dental hygienists, dental assistants, radiation therapy technologists, and nuclear medicine technologists. With the exception of dental auxiliaries, voluntary credentialing programs for these personnel are firmly established and widely accepted.[3]

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[1]For a fuller description, see R.M. Conant, "A Credentialing Concept," Journal of Environmental Health 41 (September-October): 88-91, 1978.

[2]Criterion-referenced examinations measure examinee performance against a predetermined standard instead of against the performance of other persons who take the same examination.

[3]Dental hygienists are licensed in all States. Voluntary certification exists for dental assistants, but only a small proportion of the work force is certified.

RADIOGRAPHERS (MEDICAL RADIOLOGIC TECHNOLOGISTS)

Radiographers are professionals who perform or may be called upon to perform a comprehensive scope of diagnostic radiology procedures employing equipment that emits ionizing radiation, and who are delegated or exercise responsibilities for the operation of radiation-generating equipment, the shielding of patient and staff from unnecessary radiation, the appropriate exposure of radiographs, or other procedures that to any significant extent contribute to the determination of the site or dosage of the ionizing radiation to which a patient is exposed.

As the term is commonly used, radiographers are distinguished from other individuals whose use of ionizing radiation is limited to a few specific body sites or to a limited set of standard procedures. They also are distinguished from personnel in other clinical specialties who occasionally may be called upon to assist in diagnostic radiology and from assistants or technicians whose activities do not contribute in any significant degree to the determination of site or dosage of radiation.

Certification

Two nongovernmental bodies presently certify radiographers: the American Registry of Radiologic Technologists and the American Registry of Clinical Radiography Technologists.

The larger of these -- the American Registry of Radiologic Technologists (ARRT) -- reported 129,273 certificate holders nationwide in February 1982. The ARRT grants certificates in radiography to individuals who successfully complete an examination and who meet prescribed educational requirements. Content specifications for the ARRT certifying examination are derived from an analysis of the knowledge, skills, and competencies necessary to perform as a radiographer. The examination is criterion-referenced.

In general, graduation from a formal educational program in radiography accredited by CAHEA is required of candidates who wish to sit for the examination. However, the ARRT reviews the qualifications, on a case-by-case basis, of other applicants whose education and experience meets or exceeds those of graduates from CAHEA-accredited programs. The ARRT is an independent organization with four trustees appointed by the American College of Radiology and four appointed by the American Society of Radiologic Technologists.

The smaller certifying body -- the American Registry of Clinical Radiography Technologists (ARCRT) -- reported approximately 5,000 certificate holders in July 1982. The ARCRT grants certificates to individuals who pass its examination and who meet prescribed combinations of education and experience. To sit for the examination, applicants must have graduated from a 24-month program in radiography accredited by CAHEA, or have completed an approved military program in radiography, or have passed a challenge

examination[1] offered by the ARCRT. The challenge examination is open to individuals who are trained on the job and who have the equivalent of 5 years of full-time clinical experience. The challenge examination was developed by the ARCRT in 1978.

In addition, the ARCRT will certify individuals who hold current certificates issued by ARRT and individuals licensed in radiography by States with standards equivalent to those of ARCRT.

Accreditation

CAHEA accredits educational programs for radiographers and is recognized for this purpose by the U.S. Department of Education and COPA. Virtually all educational programs for radiographers are accredited.

The American College of Radiology and the American Society of Radiologic Technologists cooperate with CAHEA in the accreditation process. These organizations collaborate in developing the Essentials and Guidelines for accredited programs and appoint members to the Joint Review Committee on Education in Radiologic Technology, which evaluates programs and recommends accreditation decisions to CAHEA. Accreditation is reviewed at least every 5 years, or more frequently if circumstances warrant.

State Regulation

Licensure. Thirteen States license radiographers, all of which specify both educational and examination requirements before a license to practice is issued. Ten of these 13 States have contracted with the ARRT to administer its examination as the State licensure examination. Four of these also will license individuals currently certified by the ARCRT if certain conditions are met by the applicant.

Three States administer their own licensure examination, one of which will also license ARRT certificate holders if the applicant has achieved at least a score of 70 percent on the radiation protection and radiologic procedure sections of the ARRT exam. Puerto Rico requires applicants who have met its educational requirements and passed its licensure examination to serve 1 year of public service before a license is granted. Table 1 shows the requirements of the 13 States that now regulate radiographers.

In addition, Delaware, Illinois, Iowa, Michigan, and Minnesota have enabling legislation for the regulation of radiologic personnel.[2] Iowa began to implement a program on July 1, 1982, that sets standards for personnel functioning as operators of diagnostic X-ray equipment in medicine,

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[1]ARCRT offers a challenge examination for individuals who do not have formal preparation in the field. Individuals who pass the challenge examination become eligible to take the certification examination.

[2]These States have statutes that authorize or could be cited as authority for programs to regulate radiologic personnel. They have not yet instituted licensure programs.

Table 1. State licensure requirements for radiographers, 1982[1]

State	Education program approved by		Other licensure requirements	
	CAHEA/JRC	or State	Exam required	or Certificate accepted
Arizona	Yes	Not at present	ARRT	ARCRT, CAHEA grads only
California[2]	Yes	Yes	State	ARRT with conditions[3]
Florida	Yes	Yes	ARRT	ARCRT
Hawaii	No	Yes	State	None
Indiana	Yes	Not at present	ARRT	None
Kentucky	Yes	Not at present	ARRT	ARCRT, CAHEA grads only
Montana	No	Yes	ARRT	None
New Jersey	Not at present[4]	Yes	ARRT	None
New York	State with CAHEA/JRC		ARRT	None
Oregon	Yes	Not at present	ARRT	ARCRT after 1974, CAHEA grads only
Vermont	Yes	Not at present	ARRT	None
West Virginia	State with CAHEA/JRC & State may approve others		ARRT	None
Puerto Rico	No	Yes	State & 1 yr. service	None

NOTES: Iowa sets standards for operators of radiation equipment, but does not issue licenses or authorizations to practice. Enabling legislation exists in Delaware, Illinois, Michigan, and Minnesota. No other States license radiographers.

[1]Information on acceptance of credentials from other States, or on "grandfathering" provisions not shown.

[2]Also accepts training and experience in lieu of formal education.

[3]ARRT certificants must have scored 70 percent on the radiation protection and radiologic procedures sections of the ARRT exam.

[4]Agreement to cooperate with CAHEA/JRC in program approval under development by State.

KEY:

ARRT American Registry of Radiologic Technologists
ARCRT American Registry of Clinical Radiography Technologists
CAHEA/JRC Committee on Allied Health Education and Accreditation/Joint Review Committee on Education in Radiologic Technology

SOURCES: Information provided to the Health Resources and Services Administration by State health officers, licensing agencies, and radiation control agencies, 1982.

osteopathy, chiropractic, and podiatry. However, the Iowa State Department of Health reports that this is not a licensure program. Legislation authorizing regulation of radiologic personnel was enacted in Illinois in August 1982. Delaware, Michigan, and Minnesota have not yet put licensure programs into effect.

Accreditation. Seven of the 13 licensure States accept graduation from a radiography program accredited by CAHEA as fulfillment of the State's educational requirements. Two other States cooperate with CAHEA and the Joint Review Committee on Education in Radiologic Technology to approve educational programs. Four States approve (or reserve authority to approve) other educational programs not accredited by CAHEA. Four States do not automatically accept or recognize CAHEA accreditation, but reserve all standard-setting and approval authority to a designated State agency. Only one State accepts experience or training other than an accredited or State-approved program of formal education as a possible method of qualifying a candidate for the licensure examination.

DENTAL HYGIENISTS

Dental hygienists are oral health clinicians and educators who help patients develop and maintain good oral health. They provide preventive and therapeutic services under the supervision of dentists. Specific responsibilities vary, depending on the law of the State in which the hygienist is employed, but in all States include exposing and processing radiographs for diagnostic purposes, among other duties.

Certification

There is no national certification for dental hygienists, since these personnel are licensed in all States.

Accreditation

Accreditation of educational programs in dental hygiene is conducted by the Commission on Dental Accreditation of the American Dental Association, which is recognized for this purpose by the U.S. Department of Education and COPA. Graduation from an accredited dental hygiene program is required for eligibility to sit for the licensure examination in all States except Alabama. The accreditation standards of the Commission include standards for curricula and instruction in dental radiography. Virtually all dental hygiene educational programs are accredited.

The Commission is composed of 20 members, including a representative from the American Dental Hygienists' Association, representatives of other disciplines whose educational programs are accredited by the Commission, and public members. Reaccreditation is conducted on a 5-year review cycle and a 10-year site visit cycle.

State Regulation

Licensure. All States require dental hygienists to successfully complete State licensing examinations in order to practice their profession. While individual States set their own licensure requirements, all require written and clinical examinations.

All States except Alabama and Delaware accept satisfactory scores on the national board examination in dental hygiene as full or partial fulfillment of the State requirement for a written examination. Additional written tests are required in all States except California, Illinois, Iowa, Massachusetts, New Jersey, New York, Puerto Rico, Rhode Island, and Utah. These additional examinations vary among jurisdictions. Alabama and Delaware require all candidates for licensure to pass an examination offered by the State, rather than the National Board. Alabama also requires a radiation safety test, which is given at the time of the licensing examination, and which must be passed in order to obtain a license.

The National Board examination in dental hygiene is conducted by the Joint Commission on National Dental Examinations of the American Dental Association and has been administered since 1962. In 1981, exposure and processing of dental radiographs, including considerations of radiation hygiene and safety, accounted for 46 items or 13 percent of the test. The examination is criterion-referenced.

State clinical examinations for dental hygiene licensure candidates include demonstration of knowledge and skills in oral inspection, dental charting, periodontal measurement, oral prophylaxis, and radiography. The weighting of these sections varies among States, but on the average, 25 percent of the examination is devoted to dental radiography.

In 1974, under a contract with the Department, the American Dental Hygienists' Association began the development of a criterion-referenced clinical examination in dental hygiene. Dental radiography accounts for 25 percent of the examination score. This test is now being used by the Central Regional Dental Testing Service (which administers examinations for 11 states), the Southern Regional Testing Agency (4 States), the Western Regional Examining Association (4 States), and State dental boards in California, Texas, Hawaii, and North Carolina.

Accreditation. Except for Alabama, all States require candidates for licensure in dental hygiene to have graduated from a formal educational program accredited by the Commission on Dental Accreditation. Alabama accepts graduates of accredited programs as eligible for the licensure examination, but also permits preceptor training of dental hygienists in the offices of designated practicing dentists. On-the-job-trained dental hygienists who complete the preceptorship program are then eligible for the licensure examination. This preceptorship program requires 2 weeks of study at the University of Alabama; 12 1/2 hours of dental radiography are included in the course.

DENTAL ASSISTANTS

Dental assistants provide a wide range of clinical and laboratory skills and functions that aid the dentist in the delivery of oral health care. While dental assistants are permitted to assume expanded functions in some States, there are considerable differences among States in the definition of these functions. However, in all States except the District of Columbia and Rhode Island, exposure and processing of dental radiographs for diagnostic purposes may be delegated to dental assistants.

Certification

The Dental Assisting National Board provides a voluntary national mechanism for certifying dental assistants. The Board operates under requirements adopted by the American Dental Association and is a member of the National Commission for Health Certifying Agencies.[1] Individuals who have successfully completed an educational program in dental assisting accredited by the Commission on Dental Accreditation are eligible to sit for the certification examination. Since 1980, on-the-job-trained dental assistants have been allowed to take the national examination as part of a study to determine appropriate requirements and methods for certifying personnel trained on the job. The certifying examination offered by the National Board is criterion-referenced.

Accreditation

Educational programs in dental assisting are accredited by the Commission on Dental Accreditaton, which includes a representative of the American Dental Assistants Association. Accreditation standards for dental assisting programs include standards for curricula and instruction in dental radiography. Reaccreditation is conducted on a 5-year review cycle and a 10-year site visit cycle. Some dental assisting programs located in proprietary schools and some military programs are not accredited by the Commission. Virtually all other educational programs in dental assisting are accredited.

State Regulation

Dental assistants are permitted to expose and process dental radiographs in all States except Rhode Island and the District of Columbia. While no State terms its regulatory procedure "licensure," 21 require dental assistants to complete specified training and/or an examination before engaging in dental radiography under the supervision of a dentist. Six of these 21 States award certificates or register dental assistants who have met their requirements in specified areas, including radiography. The remaining 29 States permit the practice of dental radiography by assistants, but have no training or examination requirements.

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[1] The National Commission for Health Certifying Agencies is a voluntary organization whose purpose is to improve the reliability, validity, and fairness of credentialing policies, procedures, and standards among voluntary agencies that certify the competence of health personnel.

Training and Examinations. Of the 21 States that regulate the dental assistant's use of dental radiography, requirements vary considerably. Some require only a specified training course, others require only an examination, while still others require both training and examination. Table 2 displays the considerable variety now existing among these State requirements.

Training requirements vary from graduation from a State-approved course in expanded functions for dental assistants (13 States), to graduation from a State-approved course in dental radiography alone (4), to graduation from an educational program accredited by the Commission on Dental Accreditation (1).

Five States accept certification by the Dental Assisting National Board as fulfillment of their requirements. Five states will permit dental radiography by assistants who have passed State-administered written and clinical examinations, and five States use written examinations only. In some States, these examinations are conducted by State dental boards or dental associations, and in others, by radiation control agencies or environmental protection agencies. The content of training courses and examinations varies among States.

RADIATION THERAPY TECHNOLOGISTS

Radiation therapy technologists, working from a prescription and with a radiotherapist, are professionals who utilize equipment that generates ionizing radiation for therapeutic purposes on human subjects. Using X-ray equipment, radionuclides, and electron beam equipment, they expose specific areas of the body to prescribed doses of ionizing radiation, assist in tumor localization and dosimetric procedures, assist in the proper operation of controlling devices and in radiation protection for patients and clinical personnel.

Certification

The ARRT provides a voluntary national system for certification of radiation therapy technologists. The ARRT awards certificates to individuals who successfully complete an examination and meet prescribed educational requirements. Content specifications for the certifying examination are derived from an analysis of the knowledge, skills, and competencies necessary to perform as a radiation therapy technologist. The examination is criterion-referenced.

In general, graduation from a formal educational program in radiation therapy technology accredited by CAHEA is required of candidates who wish to sit for the examination. However, the ARRT reviews the qualifications, on a case-by-case basis, of other applicants whose education and experience meet or exceed those of graduates of CAHEA-accredited programs. The ARRT reported 2,876 certificate holders in February 1982.

Accreditation

As is the case for educational programs for radiographers, educational programs for radiation therapy technologists are accredited by CAHEA, with the cooperation of the American College of Radiology, the American Society of Radiologic Technologists, and the Joint Review Committee on Education

Table 2. State training, examination, and credentialing requirements for dental assistants making dental radiographs

State	Required training	Required examinations			Credential issued
		Dental Assisting National Board	State		
			Written	Clinical	
Arizona	Expanded function	No	Yes	Yes	Certificate
California	Expanded function	No	Yes	Yes	Certificate
Florida	Approved course	No	No	No	Certificate
Illinois	Approved course	No	No	No	None
Indiana	Approved course	No	No	No	Certificate
Iowa	Approved course	No	Yes	No	None
Kentucky	Expanded function	No	No	No	None
Maryland	Expanded function[1]	Yes	Yes[1]	Yes[1]	Registration
Michigan	Expanded function	No	Yes	Yes	None
Minnesota	Expanded function	No	Yes	No	Registration
Montana	Expanded function	No	Yes	No	None
Nebraska	Expanded function	No	No	No	None
New Hampshire	Expanded function	No	No	No	None
New Jersey	None	Yes	Yes[1]	No	Registration
North Carolina	Expanded function	No	No	No	None
North Dakota	Accredited program	Yes	No	No	None
Oklahoma	Expanded function	No	No	No	None
Oregon	None	No	Yes	Yes	None
Tennessee	Expanded function	No	No	No	Registration
Vermont	Expanded function[1]	Yes	No	No	Registration[2]
Virginia	None[3]	Yes[4]	Yes[1]	No	Certificate

NOTES: The District of Columbia and Rhode Island do not permit dental assistants to make dental radiographs. All other States not listed above permit dental assistants to make dental radiographs without restriction.

[1]Not required if certified by the Dental Assisting National Board.

[2]Dental Assisting National Board certification accepted in lieu of State registration.

[3]State provides but does not require a home-study course in dental radiography.

[4]Accepted if applicant provides statement that he/she has completed training in dental radiography.

KEY:

Certificate	Certified by a State agency
Registration	Registered by the State dental board
Expanded function	Expanded function training course
Approved course	Approved training course in dental radiography
Accredited program	Dental assisting program accredited by the Commission on Dental Accreditation

SOURCES: Commission on Dental Accreditation, Division of Educational Measurements, Legal Provisions for Delegating Expanded Functions to Dental Hygienists and Dental Assistants (Chicago: American Dental Association, January 1981).

Analysis of State Laws Regarding Legal Provisions for Dental Auxiliaries (Lexington, Ky.: Council of State Governments, May 1982).

Correspondence from the Indiana State Board of Health and Virginia Department of Health Regulatory Boards, 1982.

in Radiologic Technology. Accreditation is reviewed every 5 years, or more frequently if circumstances warrant. Virtually all programs in radiation therapy technology are accredited.

State Regulation

Licensure. Seven States license radiation therapy technologists, and have educational and examination requirements for licensure. Of these seven States, five have contracted with the ARRT to administer its examination as the State licensure examination. One State administers its own examination, but also will license individuals who hold current ARRT certificates in the profession if they have scored at least 70 percent on the radiation protection and radiologic procedure sections of the ARRT examination. Puerto Rico administers its own examination, and requires 1 year of public service before issuing a license. Table 3 displays the current status of State requirements.

Two States have plans to institute licensure of radiation therapy technologists. In Hawaii, the program is under development, and in Indiana, it is scheduled to be developed at a later date. Florida does not license radiation therapy technologists, but issues a certificate to individuals who have completed a State home-study course in radiation protection; in this State, radiation therapy technologists can be trained in hospital-designed programs, but neither educational program approval nor licensure of personnel is required by the State.

Enabling legislation also exists in Delaware, Illinois, Iowa, Michigan, and Minnesota.

Accreditation. Among the seven licensure States, four accept graduation from a CAHEA-accredited program. Two of these four States also accept graduation from other educational programs approved by the State, and one State also accepts training and experience other than formal education as a possible means of qualifying one for the licensure examination. Of the three States that do not automatically accept the CAHEA accreditation process, one cooperates with CAHEA in educational program approval, and two reserve all standard-setting and program approval authority to a designated State agency.

NUCLEAR MEDICINE TECHNOLOGISTS

Nuclear medicine technologists are professionals who conduct *in vivo* or *in vitro* detection and measurement of radioactivity for medical purposes or who administer radiopharmaceuticals to human beings.

In vivo procedures involve the administration of radioactive tracer chemicals to the patient. In one type of procedure, the tracer is administered and after a period of time instruments are employed to measure the radioactivity emitted from the body in the vicinity of the organ in question. To accomplish this, the tracer must emit gamma radiation powerful enough to affect recording devices, but because tracers have short half-lives, irradiation of patients' tissues continues only briefly after the recording has been completed. In another type of *in vivo* procedure, a tracer is administered to the patient and, after a specified period of time, a sample of body tissue or fluid is removed, and the amount of tracer in the sample is measured.

Table 3. State licensure requirements for radiation therapy technologists, 1982[1]

State	Education program approved by		Other licensure requirements	
	CAHEA/JRC	or State	Exam required	or Certificate accepted
Arizona	Yes	Not at present	ARRT	ARCRT, CAHEA grads only
California[2]	Yes	Yes	State	ARRT with conditions[3]
New Jersey	Not at present	Yes[4]	ARRT	None
New York	State with CAHEA/JRC		ARRT	None
Oregon	Yes	Yes	ARRT	None
Vermont	Yes	Not at present	ARRT	None
Puerto Rico	No	Yes	State & 1 yr. service	None

NOTES: Florida does not issue licenses, but requires personnel trained in hospitals to complete a home-study course in radiation protection. Enabling legislation exists in Delaware, Hawaii, Illinois, Indiana, Michigan, and Minnesota. Hawaii is currently developing its licensure program. No other States license radiation therapy technologists.

[1]Information on acceptance of credentials from other States, and on "grandfathering" provisions not shown.

[2]Also accepts training and experience in lieu of formal education.

[3]ARRT certificants must have scored 70 percent on the radiation protection and radiologic procedures sections of the ARRT exam.

[4]Agreement for cooperation with CAHEA/JRC in approving programs under development by State.

KEY:

ARRT American Registry of Radiologic Technologists
CAHEA/JRC Committee on Allied Health Education and Accreditation/Joint Review Committee on Education in Radiologic Technology

SOURCES: Information provided to the Health Resources and Services Administration by State health officers, licensing agencies, and radiation control agencies, 1982.

In vitro procedures do not require exposure of the patient to radioactive materials. Some *in vitro* tests are performed by clinical laboratory personnel as well as nuclear medicine technologists.

Certification

Three nongovernmental organizations certify nuclear medicine technologists. In 1982, the Nuclear Medicine Technology Certification Board (NMTCB) reported 13,400 certificate holders; the ARRT reported 8,273 certificate holders; and the Board of Registry of the American Society of Clinical Pathologists (ASCP) reported 1,608 certificate holders. A number of individuals are certified by more than one organization.

Initially incorporated under the sponsorship of the Society of Nuclear Medicine and its Technologist Section, the NMTCB is now an independent agency and is a member of the National Commission for Health Certifying Agencies. The ASCP was a member of the National Commission for Health Certifying Agencies until 1982.

All three organizations award certificates to individuals who have successfully completed an examination and meet prescribed educational requirements. Each agency's certifying examination is based on an analysis of the knowledge, skills, and competencies required for the profession, and is criterion-referenced. In general, all three organizations require graduation from a CAHEA-accredited program in the professions, although alternative pathways exist to allow individuals with other prescribed combinations of training and experience to sit for the examination. Examinations offered by these agencies differ somewhat, and eligibility requirements for those individuals who have not graduated from accredited formal educational programs also differ.

The existence of three certifying boards for these personnel appears to have its genesis in the relative youth of the occupation, the diverse backgrounds of the individuals who initially entered the new profession, and the specialty orientation of the practitioners who supervise these personnel. The NMTCB is more closely indentified with the nuclear medicine community, the ARRT with radiology/radiologic technology, and the ASCP with clinical pathology/medical technology. All three certificates are acceptable to institutions and practitioners that employ nuclear medicine technologists.

Accreditation

Educational programs for nuclear medicine technologists are accredited by CAHEA. The American College of Radiology, the American Society of Medical Technology, the American Society of Clinical Pathologists, the American Society of Radiologic Technologists, and the Society of Nuclear Medicine cooperate with CAHEA in the accreditation process. The program review committee is the Joint Review Comittee on Educational Programs in Nuclear Medicine Technology, which includes four members of the Society of Nuclear Medicine (two physicians, two technologists) and two members from each of the other professional associations listed above. To maintain accreditation, programs are resurveyed once every 5 years, or more frequently if indicated. Virtually all educational programs for the profession are accredited.

State Regulation

Licensure. New Jersey, Vermont, and Puerto Rico license nuclear medicine technologists. New Jersey and Vermont have contracted with the ARRT for the use of its examination, and Puerto Rico administers its own examination. The two States that contract with ARRT also will license individuals who hold current certificates from NMTCB or ASCP. Vermont also requires NMTCB and ASCP certificate holders to have graduated from a CAHEA-accredited program to be eligible for licensure. Puerto Rico requires 1 year of public service, beyond State-approved training and examination, before issuing a license.

In addition, California is developing a licensure program, and Indiana has plans to develop such a program at a later date. Georgia, Kentucky, and Tennessee also have enabling legislation.

Accreditation. Of the three States that license nuclear medicine technologists, Vermont accepts graduation from a CAHEA-accredited program as fulfilling the eligibility requirement to take the licensure examination, while New Jersey and Puerto Rico reserve all standard-setting and program-approval authority to a designated State agency.

SUMMARY OF STATE REGULATION

Section 981(e) of the Act, which addresses State compliance, states:

> "Notwithstanding any other provisions of this section, in the case of a State which has, prior to the effective date of standards and guidelines promulgated pursuant to this subtitle, established standards for the accreditation of educational programs and certification of radiologic technologists, such State shall be deemed to be in compliance with the conditions of this section unless the Secretary determines, after notice and hearing, that such State standards do not meet the minimum standards prescribed by the Secretary or are inconsistent with the purposes of this subtitle."

Radiographers

Thirteen States regulate radiographers, and all 13 have standards for approval of educational programs and for personnel licensure. All 13 require specified education and examination for licensure. It appears that these States' standards are in most respects comparable and in some cases identical to the voluntary accreditation standards of CAHEA and the voluntary certification standards of ARRT. Since the accreditation and certification standards published by the Department parallel those of CAHEA and ARRT, it is anticipated that compliance will not pose a problem for these 13 States.

Dental Hygienists

Dental hygienists are licensed in all States, and all but Alabama require candidates to have graduated from an educational program accredited by the Commission on Dental Accreditation. Alabama accepts graduates from accredited

programs, and also accepts individuals who have completed a State-approved preceptorship that includes didactic and clinical training in dental radiography.

All but two States accept the results of the national board examination in dental hygiene as full or partial fulfillment of their requirements for a written licensure examination, and supplement written tests with clinical examinations. Alabama and Delaware, which do not accept the Dental Hygiene National Board examination, administer their own written and clinical examinations, which test competency in dental radiography and other areas.

Review of these existing standards indicates that compliance with the accreditation and certification standards to be published by the Department does not appear to pose a problem for any State.

Dental Assistants

Twenty-one States require dental assistants who make dental radiographs to complete specified training and/or an examination. Another 29 States permit dental assistants to make dental radiographs, under the supervision of dentists, without restriction. Rhode Island and the District of Columbia do not permit dental assistants to make dental radiographs. Among the 21 States that now regulate the dental assistant's use of dental radiography, standards of training and examination vary considerably. It can be anticipated that the problem faced by these States in complying with the accreditation and certification standards to be issued by the Department may vary accordingly.

Radiation Therapy Technologists

Seven States license radiation therapy technologists. These States have standards for educational program approval and specify educational and examination requirements for licensure. It does not appear that compliance with the accreditation and certification standards to be published by the Department will pose a problem for these seven States.

Nuclear Medicine Technologists

New Jersey, Vermont, and Puerto Rico license nuclear medicine technologists. These States have standards for educational program approval and set education and examination requirements for licensure. It does not appear that compliance will pose a problem for these States.

In addition to the States that now regulate the professions listed above and approve educational programs for these five professions, several States have legislation that could provide the statutory authority for licensure and educational program approval, and several more are now considering such statutes. Because the Department's standards have not yet been published, States have not had an opportunity to consider options for legislative and administrative action.

The CHAIRMAN. I would now like to introduce our first panel, which is comprised of representatives of the ad hoc working group to develop radioepidemiolcgical tables, better known as the Pall committee, and representatives of the National Council for Radiation Protection and Measurement Committee, better known simply as Committee 71.

The Rall committee is represented by Dr. Ed Rall, Dr. Gilbert Beebee, and Dr. Charles Land. Committee 71 is represented by Mr. Seymour Jablon and Mr. Schaffer. Actually, Mr. Jablon has the honor, or perhaps the onus, of belonging to both committees. Mr. Schaffer has the distinction of being the only attorney on either committee.

We shall begin with Dr. Rall's testimony and then move on to Mr. Schaffer, because he is under a time constraint this morning. Bill Schaffer is not scheduled to make a formal presentation, but since he is the only lawyer involved, since these tables may have a substantial legal impact, since he has had a long experience with this issue of radiation liability, both in the Government and in private practice, and especially since we have had our differences in the past, I am most interested in hearing his perspective on the tables. After Mr. Schaffer's testimony, I shall ask him several questions so that he can keep to his schedule, but then I shall save the balance of my questions until Mr. Jablon has testified on behalf of Committee 71. Of course, Dr. Beebee and Dr. Land, you are also welcome to comment at any time, and I hope you will participate actively in the questions and answers.

As always, I would like to ask the witnesses to summarize their formal statements, so that we can have more time for discussion, but we will put all formal statements of all witnesses today in the record as though fully delivered. So summaries are certainly in order. Let's turn at this time to you, Dr. Rall, and we will proceed.

STATEMENT OF J. EDWARD RALL, DEPARTMENT DIRECTOR FOR INTRAMURAL RESEARCH, NATIONAL INSTITUTES OF HEALTH, ACCOMPANIED BY DR. GILBERT BEEBEE, CLINICAL EPIDEMIOLOGY BRANCH, NATIONAL CANCER INSTITUTE, AND CHARLES LAND, HEALTH STATISTICIAN, RADIATION EPIDEMIOLOGY BRANCH OF NCI

Dr. RALL. Mr. Chairman, I am pleased to appear before you today. The development of the radioepidemiological tables was mandated by section 7B of Public Law 97-414, enacted on January 4, 1983.

To ensure, as far as possible, that these tables represent the best scientific judgment, the Secretary of Health and Human Services established the NIH ad hoc working group, three members of which are here: Dr. Gilbert Beebee of the National Cancer Institute, Dr. Charles Land of the National Cancer Institute, and Mr. Seymour Jablon of the National Academy of Science. In addition to that, Dr. Oddvar Nygaard, director of radiation biology at Case Western Reserve; Dr. Arthur Upton, professor and chairman of the Department of Environmental Medicine at New York University; and Dr. Rosalyn Yalow at the Veterans' Administration hospital in the Bronx; and Dr. Victor Zeve, executive secretary.

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I will give you some of the background underlying the preparation of the tables. I should first say that the NIH and the Assistant Secretary for Health asked the National Academy of Sciences to form an advisory committee, the so-called oversight committee, to assist the working group. This has been chaired by Dr. Frederick Mosteller, and this committee has been of great help to our committee. In addition, NRCP Committee 71, as you have noted, has been working on tables for several years, and we have benefited from their work and thoughts.

We have prepared now three draft documents. The first one in December concerned the fundamental assumptions necessary for the preparation of the tables and was submitted to the National Academy in December. We received their reply in April. We then submitted a second draft to them in July, and we have had informal communication from them since then. We are just in the process now of sending them a third draft, and we are hopeful to get a final draft, including tables, drafts and varied and assorted formulae for the calculation of probability of causation under any circumstance to the secretary early in November.

First, the working group determined it could not really review all the world's literature on radiation as a cause of cancer, particularly since in 1980, the National Academy of Sciences' Committee on Biologic Effects of Ionizing Radiation, the so-called BEIR III committee, prepared an exhaustive survey of the world literature up through 1979. So we have used that as a basis.

We have, however, had available to us some unpublished data and other published data which have led us to depart in significant ways from the BEIR III report. We have for example, developed a new so-called wave-function time-response model for leukemia and for bone cancer, which is different than BEIR III or any other one but which we think more accurately portrays the experimental data. We also have used different coefficients for thyroid cancer and breast cancer. We have added cancer of the salivary gland, which now appears fairly to the radiogenic. We have omitted lymphoma; it looks now as though the evidence is not sufficient to rank this as a radiation-induced cancer. And we have avoided probability-of-causation calculations for certain cancers following exposure at younger ages because we do not think there are enough data to support those calculations.

A brief history of radiation, which has been known for some 80 years now. The first indication that it might be harmful was when it was discovered that people working with radiation got a sunburn-like effect, radiation dermatitis. At that time, it was believed that there was a threshold, a certain amount of radiation below which there was no effect. This, by and large, seemed to be true for radiation dermatitis. A few rads did not produce it and 1,000 rads to the skin did produce it.

However, work on the genetic effects of radiation in the thirties and forties suggested very strongly that any dose of radiation had a certain possibility of producing a damaging effect on germ cells. Based on these findings, a 1954 report by the NCRP recommended that one could no longer assume a threshold. In the last 20 years, however, the concern has become much more over the effect of ra-

diation on causing cancer. This is, of course, one of the reasons for the legislation enacted for the existence of this committee.

As you pointed out in your remarks, radiation causes cancer in a largely random manner. Although we can predict when a large group of people got a large amount of radiation, we can predict with a fair degree of accuracy what fraction will get cancer of the breast, leukemia, and so on, but we certainly cannot say which individual will get the cancer. When an individual has developed a cancer, we cannot say whether it was due to radiation or not, because radiation induced cancers look no different than cancers that develop for any other reason. In fact, although we know a great deal about what might cause cancer in terms of environmental factors and genetic susceptibilities, we usually cannot tell what caused any individual cancer, with the possible exception of cigarette smoking which is the cause of the vast majority of cancers of the lung and, indeed, accounts for between 30 and 40 percent of the total cancer burden in the United States.

There were a variety of assumptions that had to be made before tables could be constructed, and I might go through them rather briefly. We first had to decide what data should be used. There is a great deal of data on the induction of cancer in experimental animals, mostly rodents. There is a considerable body of data on the effect of radiation on cells in tissue culture. Unfortunately, the problem with experimental animals is the same as it is with humans in a certain sense. To observe small effects, one needs very large numbers of animals, and this is rather difficult to manage. Even more importantly, most of the animal studies have been with inbred animals, in which there are very high or very low incidences of cancers, and it would appear that the cancer in these animals is somewhat different than the cancers that develop in human beings.

Finally, the in vitro experiments on tissue culture differ so profoundly from the results when a whole individual is radiated, there being no immune response for example, that we did not feel we could use these. Hence, we used epidemiologic data derived from radiation exposure to humans.

The second thing that had to be resolved was how to estimate the risks at low doses of radiation. We have reasonably good human data on the risks of radiation for certain cancers at relatively high doses. What is the risk at low doses? We have, except for breast and thyroid, relatively little human data on radiation doses less than 100 rads.

There are basically two methods of approaching this. One is to assume that the risk is linearly proportional to the radiation. That is to say, 1 rad will produce one-hundredth of the effect of 100 rads. For thyroid cancer and breast cancer, there are data, extending down in the case of thyroid cancer, to as little as 10 rads and in the case of breast cancer to radiation doses a little bit higher than that, which support reasonably firmly the so-called linear extrapolation hypothesis. We have used that to construct the tables of probability of causation for these two cancers.

For the other cancers, the human data fit both a so-called linear quadratic formulation in which the effect of smaller doses of radiation is less per rad than the effect of larger doses of radiation.

This formulation fits perfectly well the human data for leukemia and for several other cancers. There are some radiobiologic effect reasons that make one lean toward this interpretation. Indeed, this is what the BEIR III committee felt was the most logical way to extrapolate the effects of low doses of radiation from data at higher doses. So we have used this formulation for all of the cancers except thyroid and breast.

The third assumption the group had to make was to consider the relative effectiveness of radiation delivered at different dose rates. There are no conclusive human data on this, although the differences in dose rates range from a 10,000 to 20,000 rads per minute delivered in the bombings at Hiroshima and Nagasaki to of the order of a few rads per minute delivered in fluoroscopy, where there are data for breast carcinoma. This appears to have had relatively little effect. However, there are other data which suggest that a very low dose rate may be less effective than rather high dose rates. For reasons that I do not have the time to go into, the use of the linear quadratic formulation in general resolves the problem of dose rate, particularly when we partition radiation into units no smaller than 5 rads. So we feel that this has been resolved.

A fourth problem is the relative carcinogenicity of what is called high linear energy transfer radiation. This is a radiation delivered by neutrons or alpha particles. Neutrons one will get from a reactor and alpha particles from the decay of radium, as for example with uranium miners. It is known from a variety of experimental situations that this kind of radiation is considerably more effective in causing cancer than so-called low-LET radiations, such as x rays and gamma rays. This appears to be because the ionizing events which cause the cancer are so closely spaced that they can cause two damaging events relatively easily, whereas the ionizations produced from low-LET radiation, such as gamma and x rays, tend to be much more diffusely arranged.

All of our tables except bone cancer deal with the more commonly occurring low-LET radiation, and to use the tables for high-LET radiation certain correction factors will have to be introduced. Some of these are available in the literature, and we will give some indication as to how that can be done.

Finally, a fifth assumption required for calculation of these tables has been the relationship of the numbers of cancers produced at any time after irradiation by comparison with the number normally occurring in a similar population of the same age and sex not exposed to radiation.

The BEIR III committee used two methods to do this. One was the so-called relative-risk time-projection model, the other an absolute-risk time-independent model. The absolute-risk model assumes that the added risk of developing cancer after radiation is constant after a suitable latent period. The number of cancers will be the same, irrespective of the baseline rate. The relative-risk time-projection model states that at any time after a latent period, a given dose of radiation increases the probability of developing cancer by a constant fraction, so that the fraction will be an increase of a few percent of the natural-occurring rate, and that will be constant

even though the natural rate, as in most cancers, generally increases with age.

We have adopted the relative-risk time-projection model because the most recent data, particularly on breast and stomach cancers, quite convincingly support this model. This particularly has to do with breast carcinoma, which is quite uncommon in the twenties and thirties and then becomes very common indeed in the forties and fifties. As the experience is accumulated and the Japanese population exposed to the atom bombs at Hiroshima and Nagasaki, there is now enough experience to show that this in point of fact is exactly what happened, that there is a constant fractional increase in risk with time.

I could mention that there have been other estimates of probability of causation, or something similar, prepared by the British Nuclear Fuels, Ltd., by John Gofman and by Stewart. The British Nuclear Fuels procedure is not available to the public. Serious objections have been raised to the Gofman calculations, and the Hanford worker data used by Stewart we regard as much too fragile to provide the basis for any systematic probability of compensation table.

The draft you will see will represent a consensus of the ad hoc working group, peer reviewed by the oversight committee. I will be pleased to answer any questions that you might have at this time.

[The prepared statement of Dr. Rall follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
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STATEMENT OF

J. E. RALL, M.D., Ph.D.

DEPUTY DIRECTOR FOR INTRAMURAL RESEARCH

NATIONAL INSTITUTES OF HEALTH

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES

UNITED STATES SENATE

SEPTEMBER 18, 1984

Mr. Chairman and members of the Committee, I am pleased to appear before you today to discuss the development of the radio-epidemiological tables, as mandated by Section 7B of Public Law 97-414. This law, the Orphan Drug Act, which was enacted on on January 4, 1983, directed the Secretary of Health and Human Services to construct tables showing the probability that certain cancers result from prior exposure to doses of radiation.

To ensure as far as possible that the radioepidemiological tables would represent the best possible scientific judgment, the Secretary of Health and Human Services established the NIH Ad Hoc Working Group to Develop Radioepidemiological Tables. The members of this Group are Dr. Gilbert W. Beebe, an Expert in the Clinical Epidemiology Branch of the National Cancer Institute; Dr. David G. Hoel, Director of Biometry and the Risk Assessment Program, National Institute of Environmental Health Sciences; Mr. Seymour Jablon, member of the Advisory Committee on the Radiation Effects Research Foundation of the National Academy of Sciences; Dr. Charles E. Land, Health Statistician of the Environmental Epidemiology Branch of the National Cancer Institute; Dr. Oddvar F. Nygaard, Director, Division of Radiation Biology, Department of Radiation Biology at Case Western Reserve University; Dr. Arthur C. Upton, Professor and Chairman of the Department of Environmental Medicine at the New York University Medical Center; Dr. Rosalyn S. Yalow, Senior Investigator at the Veterans Administration Medical Center, Bronx, New York, and Dr. Victor Zeve, Special Assistant, Office of the Director, National Cancer Institute, and Executive Secretary of the Ad Hoc Working Group. As Chairman of the Working Group, I

will give you some of the background underlying the preparation of these tables.

The NIH and the Assistant Secretary for Health requested the National Academy of Sciences to form an advisory committee (the National Academy of Sciences Oversight Committee) to assist the Working Group. The Working Group, which has prepared a draft report, has benefited from the detailed criticisms of its preliminary material by the NAS Oversight Committee, chaired by Dr. C. Frederick Mosteller. The preliminary report is now being reviewed by the NAS Oversight Committee and by other interested Federal agencies. Our report will be made available to your Committee by the Department as soon as final review is completed and changes made as appropriate during the review process. A coordinated Federal response is currently being developed by the Committee on Interagency Radiation Research and Policy Coordination.

Limitations

In preparing the tables, the NIH Ad Hoc Working Group, as well as the Oversight Committee, identified the same set of problems involved in the calculation of probabilities of causation (PC) for cancer following exposure to ionizing radiation.

The Working Group determined that it could not attempt a new analysis of the epidemiologic data but should base many of its calculations on the third report issued in 1980 by the National Academy of Sciences Committee on the Biological Effects of Ionizing Radiation (BEIR III) (1) that itself had required more than three years to complete. The Working Group, however, did depart from the BEIR III report in several important details because of the avail-

ability of new data. These include adoption of a new "wave function" time-response model for leukemia and bone cancer, different coefficients for thyroid cancer and breast cancer, addition of cancer of the salivary gland, omission of lymphoma as a radiation-induced cancer, and avoidance of PC calculations for certain cancers following exposure at younger ages.

The problems recognized by both groups will be addressed in the future through the accumulation of more human data, and especially by new insights into the mechanisms of carcinogenesis. The Working Group interprets its mandate from the Orphan Drug Act as requiring assessment of currently available data and the exercise of its best judgment regarding the handling of the scientific uncertainties that are at present unresolved.

Relationship between Radiation Exposure and Development of Cancer

I would now like briefly to review some of the scientific issues faced by the Working Group and describe the decisions we made in order to be able to prepare the radioepidemiological tables.

Historically, not long after ionizing radiation was discovered and methods for producing and utilizing various types of radiation became available, it was demonstrated that exposure to large doses of radiation could be biologically damaging. First came the recognition that radiation to the skin could cause a serious, sunburnlike effect. Then it was learned that radiation could cause skin cancers.

In 1928 the International Congress of Radiology adopted the first international recommendation for radiation protection. At that time, it was believed that there was a threshold for the deleterious effects of radiation, that is, a dose below which there

would be no damage. Work on the genetic effects of radiation in the 1930's suggested that any dose of radiation had a certain likelihood of producing a damaging effect on germ cells, that is, sperm and egg cells. Based on these findings, a 1954 report by the National Committee on Radiation Protection recommended that a threshold could no longer be assumed. Concern over the genetic effects of radiation, so prevalent in the 1950's, has, in the last two decades, been coupled with a growing awareness of the effects of radiation, particularly the induction of cancer, on non-germ, or somatic cells of the body.

Radiation acts to cause cancers in a largely random manner. In a situation in which a large number of people have received a moderate to large amount of radiation, the numbers of specific cancers (e.g., breast cancer, leukemia, etc.) produced by that amount of radiation can be statistically estimated. We cannot, however, predict which individuals will develop cancer. Even after the cancer has developed, we cannot state with certainty whether it was caused by radiation, since it is impossible to differentiate cancers induced by irradiation from those which occur "normally" in the population.

Cancer appears to be caused by a large number of environmental factors and genetic susceptibilities although, in any individual case, it is usually not possible to be sure of the exact cause of that cancer. The events that may cause or predispose an individual to develop cancer interact in several ways, but only a few of these interactions are known and understood.

Moreover, different individuals are exposed differently to

greater or lesser carcinogenic factors as the result of cigarette smoking, alcohol consumption, viral infection, dietary habits, occupation, etc. If detailed knowledge were available about the effects of all these exposures and interactions, it would be possible theoretically to classify individuals into a large number of groups in which the probability of causation of a given cancer could be calculated with greater accuracy. For radiation carcinogenesis, however, the number of such groups is limited at present; i.e., from available data we can, with some assurance, partition populations into categories based on a few factors, including age, sex, smoking history and age at exposure to radiation. Except for these subdivisions we can calculate probabilities of causation only for aggregated groups. However, a lack of precision in partitioning has no effect on the sum of the probabilities for the entire population. Given these limitations on the validity of the radioepidemiological tables, no court should consider the tables reliable evidence that a specific individual's cancer was caused by radiation exposure.

Attempts to estimate the probability that an observed effect resulted from one of several possible causes are not uncommon, even in the more exact physical sciences. Decay of short-lived exotic particles in physics, where only a small number of events can be observed and several potential mechanisms exist, is in some respects analogous to the problems involved in constructing radioepidemiological tables. In both cases, probabilities are calculated from a small number of events.

There is, however, an important difference. In physics a

large number of well-tested and comprehensive theories exists to guide calculations, whereas in biology and medicine there are almost no well-established general and predictive theories. This becomes particularly important for calculation of the probability that radiation caused a certain cancer when the dose of radiation was small and/or was given at a low dose rate.

Low Dose Estimates

Several government reports, such as the 1979 Report of the Work Group on Science of the Interagency Task Force on the Health Effects of Ionizing Radiation (2), the 1981 report of the Comptroller General to the U.S. Congress (3), and the 1981 report of the Interagency Radiation Research Committee (4), as well as such authoritative reports as the BEIR III report of the National Academy of Sciences (1), and the 1977 report of the United Nations Scientific Committee on the Effects of Atomic Radiation (5), testify to the uncertainty of the carcinogenic effects of very low doses of radiation. Although effects at moderate to high doses can be estimated reasonably well in large populations, the lower the dose the more uncertain any estimate becomes.

Some of these environmental and occupational doses are quite small, on the order of natural background levels to which we are all exposed (about 0.08 to 0.2 rad per year in the United States), and it might be supposed that studies of populations living in regions where background levels vary greatly would yield estimates of carcinogenic risk associated with such differentials. Several such studies have been attempted, but they have provided little information since the risks are so low that any effect is swamped by the natural

variation in cancer incidence (5,6,7). Nor can the absence of positive findings be taken as firm evidence that dose-response functions for cancer are characterized by threshold doses below which the carcinogenic effect is absent. At the present time, estimations of effects at low doses are based upon assumptions as to the mathematical form governing the dependence of effect upon dose, since we must extrapolate from the dose region where we do have reasonably stable estimates of effect, to the region where data are unavailable.

In general, the Ad Hoc Working Group utilized epidemiologic data derived from radiation exposure to humans. However, there is a large body of data on radiation effects in experimental animals, largely rodents, and additional data from *in vitro* studies of effects of radiation on cell cultures. The animal data on low levels of ionizing radiation are constrained, however, by the same limitations as the data on humans--the difficulty that the small effects require very large numbers of animals. Furthermore, the studies on rodents have been restricted almost entirely to highly inbred strains of animals and to types of tumors that occur with high frequency. Hence their relevance to the carcinogenic effects of low-level irradiation in the human population is uncertain. The *in vitro* experiments suffer, similarly, because the cells are studied under conditions that differ profoundly from those *in vivo*, and the experimentally induced effects of irradiation are of uncertain relevance to the carcinogenic effects of irradiation *in vivo* (8).

Methodology for Models

For calculations of the carcinogenic effects of low doses of

radiation, the Working Group has used the simplest dose-effect models consistent with the human epidemiologic data. For leukemia and bone cancer, the data are consistent with a so-called linear quadratic model, and this is the basis for the tables for those cancers. This model utilizes two constants and, in general, predicts that small doses of radiation have a lesser effect per rad than higher doses. There are radiologic reasons for assuming a linear-quadratic dose extrapolation generally, which are discussed both in BEIR III and in detail in Chapter III of the draft report. We have accordingly used this approach for all cancers except thyroid and breast. For carcinoma of the breast and thyroid, the data appear best described by a simple linear relationship in which the carcinogenic effect of radiation is directly proportional to the dose. Again, the tables reflect this assumption.

Although there are no conclusive human data on the health effect of radiation delivered at a very low rate relative to that delivered at a high dose-rate (atom bomb survivors, therapeutic radiation), several national and international bodies have suggested that low linear energy transfer (LET) radiation given at a low dose-rate is considerably less carcinogenic than the same amount of radiation delivered at a high rate (4,5). If a linear-quadratic model is used for extrapolation to low doses, no dose-rate correction is necessary, given a certain partitioning of protracted radiation (see Chapter V).

Another problem requiring resolution is the relative carcinogenicity of high LET radiation. This is the radiation delivered by large, highly energetic particles such as neutrons or alpha particles.

For the same total amount of energy delivered, this kind of radiation appears to be more effective in causing cancers than an identical amount of low LET radiation, such as that delivered by X rays or gamma rays. All of our tables deal with the more commonly occurring low LET radiation. To use the tables for high LET radiation, certain correction factors called "quality factors" must be used. These values will depend on the precise energy of the particles and the tissue distribution of the radiation and can best be calculated in each individual case. The alpha particle radiation received by uranium miners has usually been quantitated in working level months. How to relate this to the rad dose for LET radiation, as displayed in the tables, is discussed in Chapter III.

An additional assumption required for calculation of PC values is the relationship of the number of cancers produced at any given time after radiation in comparison with the number normally occurring in a similar population of the same age and sex not exposed to radiation. The BEIR III report utilized both a relative risk time projection model and an absolute risk time independent model. The relative risk time projection model states that, at any time after a latent period, a given dose of radiation increases the probability of developing cancer by a constant fraction. Available data, particularly on breast and stomach cancer in Japanese exposed to the atom bomb, which appeared after the preparation of BEIR III, support the relative risk time-response model even more convincingly. Therefore, the Ad Hoc Group has adopted this assumption. Chapter III of our report deals with this subject in greater detail.

Other estimates of probability of causation, or their equiva-

lent, have been prepared, to our knowledge, by British Nuclear Fuels, Limited (BNFL), by Gofman (9), and by Stewart (10), based in part on the report by Mancuso, Stewart, and Kneale (11). The BNFL procedure is not available to the public, and certain objections have been raised to the Gofman and the Mancuso-Stewart-Kneale systems of calculations (12,13,14). The present draft represents a consensus of the Ad Hoc Working Group, peer-reviewed by the Oversight Committee of the National Academy of Sciences.

Summary of the Draft Report

Chapter I outlines the Congressional actions that mandated its preparation, Chapter II describes briefly what is known about human cancer, and Chapter III how radiation relates to cancer. In Chapter III we also list those cancers which may be caused by radiation and for which adequate data are available to calculate probabilities of causation (PC), and discuss those for which an association with radiation is not proved. Chapter IV describes concepts involved in calculating the probability that any given amount of radiation was the cause of any particular cancer. In Chapter V, we explicitly list data sources and assumptions that are required for calculations of PC values and justify these choices. Chapter VI describes how the calculations have been performed. Chapter VII deals with the uncertainties associated with these calculations. Although we emphasize these uncertainties, in fact Lewis, more than a quarter of a century ago, calculated the radiogenic risk (absolute) for leukemia as about 2 cases per rad per 10^6 person-years (15). These values do not differ greatly from those we calculate today with better data at our disposal. Chapter VIII

discusses how these estimates may be updated and describes what new information may be available, and how it might be handled. Chapter IX gives the general form for calculating the probability of causation. Finally, Chapter X presents calculational routines and gives various examples of their usage for each radiogenic tissue. These site-specific tables and graphs are subdivided by sex and preceded by explanatory material describing any special features involved in the radiogenicity of that cancer, as well as the sources of the data. In addition to material which permits calculation of PC for any age and dose of radiation, we also have actual tables of PC for certain ages at exposure and for 1, 10 and 100 rad exposure. This arrangement has necessarily given rise to some redundancy, but the Ad Hoc Group believes that the present format permits anyone to obtain all the basic information for calculation of PC for a specific cancer in any specific case from just one part of the report.

I would be pleased to answer any questions you may have at this time.

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The CHAIRMAN. Thank you so much. I am going to move to Mr. Schaffer at this point because of his schedule. I will ask Mr. Schaffer questions, and then we will move to Mr. Jablon.

Mr. Schaffer.

STATEMENT OF WILLIAM SCHAFFER, ATTORNEY AT LAW, WASHINGTON, DC

Mr. SCHAFFER. Thank you, Mr. Chairman. My name is William Schaffer. I am an attorney in the private practice of law in Washington, DC. From 1977 through 1980, I was Deputy Assistant Attorney General of the Civil Division of the Department of Justice, and in that capacity I chaired, in 1979 and 1980, the Interagency Task Force on Radiation Related Illnesses, which produced a naive and unsubtle variation of the methodology that is being discussed today. From 1980 to 1981, I was special litigation counsel in the Department of Justice, Civil Division, and in that capacity acted as lead counsel for the Government in the case of *Allen* v. *United States*. I am presently active in the defense of civil radiation injury cases. I am a consultant to certain injury groups. I am, as you stated earlier, a member of NCRP Committee 71, but I am not here on behalf of any client or any organization. The views which I state and the biases, if any, are solely my own.

I appreciate the invitation to appear before the committee, and I congratulate the committee chairman for the flexibility demonstrated over the years that I have been observing this issue in changing the approach to the problem and also for expending the time and effort necessary to understand and to incorporate the current scientific evidence into proposed resolutions of this problem.

I thought what I might best do to assist the committee is to give you some general observations as to the nature of the problem, to mention briefly what I see going on in the courts and the compensation boards, to express certain thoughts or perhaps recommendations concerning the use of the tables, and to make myself available for questions. I do not have a prepared statement, but I do have a paper which I have given to Mr. Preston, which it may be appropriate to incorporate into the record. It is a paper I presented in Philadelphia and covers in detail a number of the thoughts and subjects which I will only touch on.

The CHAIRMAN. We are happy to have that. Without objection, we will place that in the record as though delivered here today.

Mr. SCHAFFER. Thank you, Mr. Chairman.

My concerns here go far beyond the question of who wins a particular lawsuit or even the broader question of whether a group of people or a special class of injuries is deserving of a specific kind of compensation. I think what is going on as the legislatures, both State and Federal, courts and compensation boards attempt to grapple with this issue has far broader ramifications.

First of all, the cases, as with anything nuclear, get a great deal of publicity. The publicity often misstates what is going on, but nevertheless, it is there and it affects the public. To give just one example, in the *Allen* case, the case involving the people who lived downwind from the Nevada testsite, the week the trial began, Newsweek magazine stated:

The case was sure to raise questions about the safety of current military and commercial nuclear programs and about the credibility of the Government agencies responsible for them.

I would submit, that case has nothing to do with current civilian nuclear power or the credibility of agencies charged with regulating nuclear power today or with military programs.

That type of publicity takes a toll, and it is for that reason that it is important, to the extent that any of us can do anything about it, that the decisions reached in the legislatures, the courts, and the compensation boards, to the extent possible, comport with good science and with good law.

We do have an energy problem in this country, and we have an ongoing debate on nuclear power. There are questions, obviously beyond the scope of this hearing, which are going to have to be answered. To the extent that we allow misinformation about the health hazards of low-level radiation to escape from this issue, to come out of these cases, we are prejudicing that debate, possibly to all of our detriment.

There are other issues where there is what I would call an adverse public education effect. I think the statistics would indicate that by far today the largest exposures to ionizing radiation are through medical exposures. Routine and nonroutine diagnostic medical procedures involve exposure to ionizing radiation, sometimes in levels higher than what we consider to be permissible in an occupational setting. With the current misunderstanding, with the current lack of knowledge, with the current credibility that, unfortunately, is being given to some of the experts who offer simplistic solutions, we could very well be getting to a point where physicians will forego valuable diagnostic x ray and other procedures for fear of lawsuits.

I think that these considerations are important. It is difficult. There are simple solutions to this, but I think this committee has already demonstrated that it is not looking for the simple solution. We owe everyone the best and clearest education we can give on the relationship between low-level ionizing radiation exposure and cancer.

There are problems for the industries who use ionizing radiation exposure. Right now, we lawyers who are involved in the issue do not know what the ground rules are. As you indicated in your opening statement, we really cannot advise our clients, nor can plaintiffs' attorneys. The result of that, I think, is that we have no way of dealing with the costs that are involved. I do not know how, perhaps Mr. Marrone will state later, the insurance company sets premiums. We really cannot, under the present system, make an evaluation of just what the risks are, what the probabilities are of winning or losing lawsuits.

Unfortunately, the returns that are coming in—at least in the cases that I am looking at, largely from the workers' comp boards but also from the courts—are not very promising. I think this area is a very apt illustration of the truism we all heard in law school that bad cases make bad law. That is what I think is happening. I think the *Allen* decision, which is obviously a case a lot of time and attention was put into by all parties, involved a 400-and-some-page opinion, a prodigious effort on the part of the judge, reached a

result which cannot be reconciled with traditional tort law concepts. I suppose the validity of that statement ultimately will be determined by the court of appeals.

But the broader concern there is that this decision offers no predictability, either to future claimants in that case or future claimants in other cases. Again, we have had the largest radiation injury case tried in the United States, one which all sides expended prodigious amounts of resources, the trial judge did a very thorough job, and we really do not know what rules are to be applied or what the result is going to be in the next case. That is a serious problem.

The workers' compensation decisions, the results are even more disturbing. In part, this is because the workers' compensation boards are not geared up to deal with these problems. The cases are tremendously complex to present, if they are presented properly. There are tremendous transactional costs, which are my fees. I may be talking myself out of a job, but I think expending this kind of effort in these cases, if they begin to come in large numbers, is going to topple the system. I do not think the system can stand it. These workers' compensation boards are set up primarily to deal with occupational injuries. They are high-volume courts, designed to obtain fairly quick results.

As an example of the kind of problems that you get, I will mention one worker's compensation decision, the case of *Hughes* v. *Berkeley Laboratories* in California, which is mentioned in my paper. There, the court made the statement—which was given, unfortunately, by one of the experts—that the issue was not whether the radiation caused the cancer but how much of the cancer did the radiation cause. My medical colleagues tell me, that is absolute hogwash. The results of that from a legal point of view, if that decision is upheld in California and adopted elsewhere, is that basically you will wind up paying—the utilities and other groups which wind up with low-level radiation exposures to their employees—will wind up paying for every case of cancer that is contracted by their employees. That is a form of health insurance; and if that is what we are going to do, we ought to call it that.

It is this kind of publicity, and it is this kind of misstating of the scientific evidence that I think is doing a grave disservice, really, to everyone. I think the problems are going to get worse as the volume of the cases increases. What we see happening because of the volume problem is both the courts and the compensation boards are exhibiting a tendency to give undue credence to those witnesses who offer a simple yes or no answer. Both in the *Allen* case and the in the *Hughes* case and in the other cases, we see references not to learned treaties but to a book that was put out by one of the expert witnesses, John Gofman, who appears with great frequency in these cases, published by the Sierra Club and subjected, as I understand it, to no peer review whatsoever.

With respect to the use of the tables, I do feel that there is promise in the tables. I have to leave it to others to state precisely how the tables should be used, what their limitations are, and the like. But I have, I suppose, three basic observations, which relate both to S. 921 and to how the tables might be used in future proposed legislation.

No. 1, I feel that it would be a grave mistake to legislate these tables into the tort law. The probability of causation approach has been used in tort cases. It has also been misused. I think that the courts are going to have to sort out the rules and the circumstances under which these tables or other such tables can be used or are admissible in those cases. I really do not think that in an effort to deal with the situation of the downwind people or others, we should do anything which could, even arguably, be construed as changing the tort law. We would be wreaking havoc in a general system in order to deal with a particular problem.

My recommendation would be that if the tables are to be used, they be used in connection with an administrative type of remedy that is limited to the problem at hand.

Second, I would suggest that there is a danger. I believe that the tables do have a use. I believe it is a limited use. I think we get into trouble when we try to legislate global solutions. The problems of the individuals who resided downwind from the Nevada testsite are different from the problems raised by the uranium miners. It is also different from the problems raised by agent orange and Love Canal and people exposed to other toxic substances.

I think there has been an unfortunate tendency to look for the simple panacea-type solution in an attempt to design systems—and I am not necessarily speaking about this committee but other proposals that have been suggested—to try to deal with all these problems with a single stroke. I do not think it can be done, and I think there is a real danger, because of the lack of precedent in this area, that if it is not made clear when the remedies, if any, are enacted that they are designed to deal with a single situation and that situation only and are not to be construed as precedent, we are going to find that they are being construed as precedent and perhaps applied in situations where they should not be applied.

I applaud the committee in its turning to science to look for answers to these problems, but I think it is important to allow full peer review of the scientific method, and it is vitally important to understand the limitations that are inherent in these doctrines. If we use science to deal with what may well be a social problem, we should say that, we should say what the limitations are. As I say, and as Dr. Rall alluded to, there are alternatives to the tables being promulgated by Drs. Stewart, Gofman, and other people. I think it is in part incumbent upon congressional committees that turn to the tables and use the tables, unless it is made clear exactly how the tables can be used and, more importantly, what their limitations are, there is a real danger that the courts will then turn to less scientific tables or adopt these tables and use them in situations in which they were not designed to be used and should not be used.

Thank you, Mr. Chairman.

[Information supplied by Mr. Schaffer follows:]

Medical/Legal Aspects of Claims of Radiation Induced Cancer

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Claims for Illness or Injury Arising from Exposure to Low Level Ionizing Radiation: An Overview

by

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I. Background

As the anti-nuclear movement has gained strength, so has the media attention given claims alleging injury from occupational radiation exposures. Today issues relating to nuclear energy, whether technical, financial, or legal, receive prominent press coverage. Unfortunately, this coverage tends to pander to the anti-nuclear mentality which, in many instances, is the only reason that the events are considered newsworthy in the first place.

Two examples illustrate the nature of this publicity: First, in 1979, nearly one thousand residents of the states of Utah, Arizona, and Nevada filed a lawsuit in which they claimed that they or their deceased relatives contracted various forms of cancer as a result of exposure to radioactive fallout from the atmospheric weapons testing program in the 1950s. Both the filing of the case and subsequent pre-trial developments were widely reported in the national press. The size of the lawsuit, as well as the historical significance of many of the events at issue therein, did warrant media attention even in the absence of the nuclear issues. The nuclear issues, however, were what captured the attention of the press. In September 1982, Newsweek magazine described the impending trial as "the litigation of the century," and stated that the case "[was] sure to raise questions about the safety of current military and commercial nuclear programs and about the credibility of the government agencies responsible for them." The lawsuit of course had nothing to do with either current military or

commercial nuclear programs. Unfortunately, however, the focus of the article illustrates the extent to which the familiar mushroom cloud still dominates the public perception of nuclear power.

The second example involves two Canadian nuclear workers who were awarded compensation for cancer under the Canadian Workers' Compensation program. A front page story in the Washington Post stressed the fact that the mens' exposures were below the applicable occupational exposure limits for U.S. workers. The statement was correct but entirely misleading. The first worker had been employed in the nuclear industry for 28 years and had received a cumulative exposure of over 100 rem. The second worker had spent 31 years in the industry and had accumulated an occupational exposure of between 100 and 150 rem. Neither individual had ever been exposed to more than 5 rem per year. Thus, while the statement was technically correct, the men had each accumulated unusually high exposures which often approached the maximum permissible annual exposures, and were thus far from typical workers. The implication of the article that their cases in some way called into question the validity of the U.S. occupational protection standards was totally unwarranted.

The result of this type of publicity is to increase the number of lawsuits for two reasons: The first relates to the increasing tendency in our society to seek to blame someone for everything which happens to us. In the Utah ligigation, for example, the claimants were asked during pretrial discovery whether they felt that the government was responsible for their (or their deceased relative's) cancer, and if so, why? Almost uniformly, the response was to the effect that there was no other reason why the claimant should have contracted cancer. The possibility that the illness had occurred without the intervention of a human agent was simply not considered. Publicity such as that described above is suggests to present and future cancer victims an explanation of why they contracted cancer.

The second reason relates to the legal system,and the manner in which legal services are marketed. Personal injury claims are usually brought under contingent fee arrangements, i.e. arrangements wherein the lawyer receives a fee only if his client is successful. The result of this system has generally been to deter the filing of complex lawsuits, unless the recoverable damages were substantial and there was a good liklihood of success. Most lawyers were and remain unwilling to devote several years of their practice and to advance substantial litigation costs unless the the chances of success and size of the potential payout justified the risk. Until recently, radiation injury cases were not perceived to meet these requirements, and hence few attorneys were willing to invest the time and effort necessary to effectively litigate them. The effect of the increased publicity has been to encourage the filing of suits, in that it has tended to create an impression that the cases are winners, and that there are other attorneys who are experienced in the field to

whom the neophyte can turn for assistance. In addition, the extensive media coverage of these cases provides added inducement for an attorney to accept a radiation injury claim in potential publicity for the attorney and his firm. The costs of bringing the cases are lowered, and the apparent chances of success and the potential rewards are increased.

Although it is difficult to estimate the actual number of claims pending at present, the increasing trend is demonstrated by reference to the claims experience of the nuclear insurance pools. In the first twenty years of the pools' experience, and prior to the accident involving Three Mile Island Unit Two (TMI), thirty nine incidents were reported, of which twenty eight resulted in covered claims. In the five and one half years following the TMI accident, seventy additional incidents were reported. The reporting rate thus increased from approximately one and one-half claims per year to an average of one claim per month since TMI.

It is also interesting to note that in the claims tracked by the pools, the average recorded exposure of workers filing radiation injury claims is less than three rem.

At the present time, most of the pending claims involve exposures sustained ion an occupational setting. (The only significant exception is the Utah litigation mentioned earlier and described more fully below.) The experience with the occupational cases, provides guidance for medical, offsite, or other types of claims which are likely to arise in the future.

In order to understand recent developments in this area it is necessary to review briefly the two basic systems through which individuals may seek compensation for occupational injuries or illnesses. The primary means by which an injured employee seeks compensation from his employer is through workers compensation programs. Workers compensation statutes have been enacted to protect virtually all workers in the United States in the event of an injury or illness sustained in the course of their employment. The goal of these systems is to provide reasonably certain benefits, inexpensively and expeditiously. The amount of compensation provided under these statutes is set forth in published schedules, and is generally well below the amount of damages which a similar injury or condition might generate in a lawsuit; the workers compensation plans dispense with any requirement of proving negligence or fault on the part of the employer; certain defenses otherwise available to the employer are abolished; and the claims, if contested, are tried before an administrative tribunal rather than a court of law. In virtually all workers' compensation systems, the relief provided to the injured employee is the "exclusive remedy" available to the employee against his employer.

Where the employee contends that his injury or illness is the fault of someone other than his own employer, he or she

may seek damages in a common law "tort" lawsuit. Unlike the workers compensation system, the injured party (the plaintiff) in a tort suit generally must prove negligence or some other form of misconduct on the part of the party he contends is responsible for his injury (the defendant), in a court of law. Notwithstanding the stricter standards of proof, delays, and uncertainties, the tort action is deemed advantageous to the injured party because it permits him to recover far more generous damages than the benefits available to him under workers compensation. For this reason, it is not uncommon, in cases of serious occupational injuries or illness, for the injured party to seek both compensation benefits from his employer and tort damages from some third party, such as an independent contractor, a manufacturer of a component or tool in use at the place of employment, or some other entity involved in the workplace environment or the activity the plaintiff alleges to be the cause of his injuries or illness.

Common to both the workers compensation and tort systems is the requirement that the claimant demonstrate a causal relationship between his injury or illness on the one hand, and his employment, in a compensation claim, or the negligence or other misconduct of the defendant, in a tort suit, on the other. In workers' compensation this requirement is generally stated in terms of demonstrating that the injury be "work related;" that it be sustained "in the course and scope of employment;" or some similar language usually found in the statute. In a tort case, the requirement is that the plaintiff must prove that the defendant's misconduct was the "proximate cause" of the injury. "Proximate cause" is generally defined in one of two ways: The definition most commonly used is known as the "but for" test, in which the plaintiff must prove that his injury would not have occurred but for the defendant's misconduct. In the alternative, in situations in which there are multiple causes of a particular injury, proximate cause may be established by proving that the defendant's conduct was a "substantial factor" or "material factor" in causing the injury. In both systems, the burden of establishing this causal relationship is initially on the claimant or plaintiff; and if he is unable to sustain this burden, relief is denied.

Thus, although the terminology is different in the two systems, a moment's reflection makes it clear that at least in the situation with which we are presently concerned, ie radiation injuries, the issue is identical. Consider, for example, the situation in which a worker receives a low level radiation exposure in the course of his employment at a nuclear facility. Assume that ten years later the same individual is diagnosed as having leukemia. The individual (or his widow after his death) files a claim for workers' compensation, alleging that his leukemia was "work related." If his leukemia was in fact caused by the exposure he recieved while at work, it is "work related" and he should recover benefits; if his leukemia was caused by exposure to some other potential carcinogen, or if it was a "naturally occuring" leukemia (assuming that the two are different) he

should not recover.

The difficulty, of course, is that a radiation induced leukemia is clinically indistinguishable from a naturally occuring illness or one caused by exposure to another carcinogen. If the worker were able to establish that his leukemia was "work related," he would establish proximate causation in the tort sense; if he were able to prove that his leukemia was "proximately caused" by his occupational radiation exposure, he would also establish that it was "work related." Proof of causation, whether stated in the terminology of workers compensation or of tort law, is equally impossible, and therein lies the problem.

II. Recent Developments

As radiation injury cases first began to appear before compensation boards and courts, the cases were not widely reported. The few reported judicial opinions found little difficulty with denying recovery based on the impossibility of establishing causation. Workers' compensation tribunals would often sidestep the causation issue in cases they deemed sympathetic by accepting the "opinions" of medical doctors as to whether a given cancer was, or was not, related to an occupational exposure.

Recently, however, as the number of claims and the publicity which they are accorded have increased, the courts and compensation boards are being forced to confront the problem. Given the current climate of public opinion and general lack of knowledge regarding radiation risks, as well as the unfortunate juxtaposition of a cancer victim or his survivors against a perceived to be wealthy nuclear utility or insurance carrier, it is unrealistic to expect judges, jurors, and those charged with administering workers compensation programs to deny recovery based on the "technical" impossibility of proving causation. Within the past several years we have witnessed increasing efforts on the part of these institutions to stretch the law, the facts, or both, in an effort to provide compensation for individuals claiming injuries or illnesses resulting from radiation exposure. The result has been a series of decisions which cannot be reconciled with either science or legal precedent. Although the outcome of these cases is distressing, the disregard for established norms of adjudication and the resultant decline in predictabilty of outcome portends grave consequences, not only for the nuclear industry but also for other industries involved with potentially toxic substances.

The following four cases illustrate the lengths to which claims agencies and courts have gone to distort fact, science, and sound and well established precedent in their efforts to award compensation or damages in these cases. The first two cases are taken from the files of the Veterans Administration (V.A.), which administers benefit programs for former members of the U.S military forces. These benefit programs operate in essentially the same manner as the workers' compensation programs

described earlier. During the weapons testing program of the 1950s and early 1960s, a number of simulated military maneuvers were conducted immediately following the detonation of nuclear weapons. In addition, military personnel were heavily involved in the testing of nuclear weapons in the Pacific Test Site. In the late 1970's, the V.A. was increasingly confronted with claims by former participants in such programs claiming that their radiation exposure during service had caused them to develop cancer and a number of other diseases. In 1981, for example, the agency reported 114 active radiation injury claims, of which over 50% involved various forms of cancer. In addition, as the number of such claims increased and became the subject of increasing pressure from constituents, a number of prominent Members of the Senate and House of Representatives began publically expressing concern with the manner in which the V.A. was handling these claims, and with what they believed to be an excessive number of claims which were being denied.

During one 1982 congressional hearing, Veterans Administration officials testified that they had awarded benefits to 16 former participants in the military weapons tests, and subsequently made public copies of its opinions in 12 of the 16 cases. Although the V.A. was being criticized for the claims it had denied, the opinions in the few cases in which it had awarded benefits were profoundly disturbing. In not one of the 12 cases did the total recorded cumulative exposure exceed 5 rem; indeed, most involved exposures of less than one rem. While the minimal exposures in these cases were disturbing, the reasoning of the Board of Veterans Appeals supporting their decisions is appalling. Two examples illustrate the point:

The first case involves a veteran (D.E.C.) who was present at the Nevada Test Site for two months during the 1957 test series. His recorded exposure was 655 mr. gamma and 84 mr. beta. In 1976, he was diagnosed as having hairy cell leukemia. In finding that his illness was "service related," the Board explained as follows:

> The issues before us involves the question of whether hairy cell leukemia was caused in part by exposure to ionizing radiation in service ... To this date... [hairy cell leukemia] has not been statistically associated with exposure to radiation. ... The apparent absence of this disease in the literature of radiation assoicated illnesses does not rule out the possibility of such relationship. It may be the case, then, that hairy cell leukemia, like some other leukemias, can be induced exclusively or in part by ionizing radiation. The appellant was exposed to an indeterminate amount of ionizing radiation during the atomic bomb testing in 1957. While participating in these tests he suffered an unexplained nose bleed and a bout of prostatitis. He was subsequently found to have a bleeding tendency on a dental examination. We may

> never be able to determine with certainty what relationship, if any, the radiation bore to the leukemia. But from a legal standpoint, the circumstances of his case raise a reasonable doubt that his exposure to radiation, and such other unknown factors as may occurred before or after service, resulted in hairy cell leukemia. We cannot exclude radiation as a reasonably probable factor.

As noted earlier, this individual's exposure records indicated a cumulative exposure of 655 mr. gamma and 84 mr. beta. For reasons which remain unclear, the Board decided to ignore the records and to characterize the exposure as "indeterminate." The Board's reasoning on causation appears to be that since radiation cannot be excluded as a possible cause of this form of leukemia (even though there is absolutely no evidence to suggest that it may be radiation related), it will be treated as if it is in fact the cause.

The second case involves a veteran (O.E.K.) who was exposed to 3.4 mr. gamma radiation while a participant in the Pacific test series. He subsequently developed malignant lymphoma. The Board's Opinion quotes extensively from the testimony of John Gofman and Alice Stewart, (who are now appearing with great regularity in our radiation injury litigation), and concludes as follows:

> The experts whose opinions are of record propose various estimates of the probability that the veteran's malignancy was caused by his radiation exposure. These risk estimates range from one in three to one in one hundred.
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> * * * *
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> An assumption common to most of the opinions is that the veteran's malignancy was a lymphoma. ... It may have been a leukemia. It is generally agreed that leukemia is more susceptible to radiogenesis than lymphoma. The exact degree of difference is unknown, but radiogenic leukemias would be expected to outnumber radiogenic lymphomas by at the very least four to one. Therefore the various risk estimates should be increased by an appropriate factor.
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> * * * *
>
> The expert opinions of record do not dispute the <u>possibility</u> that radiation caused the veteran's disease; rather it is the degree of probability that is in question. The experts' estimates of this probability vary from 1 in 100 to 1 in 3. ...from a legal standpoint, the circumstances of his case raise a reasonable doubt that his exposure to radiation was a probable factor in the development of the malignancy.

The Board thus relied heavily on the testimony of Drs. Gofman and Stewart, disregarding the reports of the other experts; ignored the film badge readings, and characterized the exposure as "indeterminate" because of the absence of data as to internal exposure; assumed that the illness was one other than that reflected in the official diagnosis; and found no significance between a 1% probability and a 33% probability, in order to reach the conclusion that radiation exposure was "a probable factor in the development of the malignancy."

After reading these two opinions, one is left with the conclusion that such reasoning would support a finding of causation in any case. Fortunately, the opinions of the Board of Veterans Appeals are not considered as precedent, even by the Board itself. Nevertheless, the V.A., because of its status as an agency of the federal government, has recourse to some of the nation's foremost scientific institutions, such as the National Academy of Sciences, the National Cancer Institute, the Armed Forces Institute of Pathology, and others, for assistance in these cases. In view of the availability of these resources, which are not as readily available, if at all, to the many state and other bodies adjudicating workers' compensation claims, the disregard of scientific evidence apparent in these V.A. opinions is all the more disturbing.

The next case is taken from the records of the Workers' Compensation Appeals Board of the State of California. In Lewis Hughes (deceased) v. Lawrence Berkeley Labs and State Compensation Insurance Fund, (No. 80-SJ-76443), Mr. Hughes widow claimed that his death from malignant lymphoma was caused by his exposure to ionizing radiation at the Lawrence Livermore Laboratory. Mr. Hughes had been employed at Livermore as a health physicist from 1956 through 1965. During the course of his employment, according to laboratory records, Mr. Hughes accumulated an exposure of 8.57 rem of whole body ionizing radiation. In 1978, at age fifty, and thirteen years after leaving the laboratory, Mr. Hughes was diagnosed as having malignant lymphoma, from which he died in December, 1979.

The issue was whether the illness was "work related" i.e., was his lymphoma caused by Mr. Hughes' exposure to ionizing radiation in the course of his employment at the laboratory. The principal witness for the laboratory (the employer) was Marvin Goldman, PhD, Director of the University of California Laboratory for Energy Related Health Research. Dr. Goldman testified that the probability that Mr. Hughes'illness was caused by his radiation exposure "ranged from a high of about 1% to about .1%."

The claimant's principal witness was again the ubiquitous Jon Gofman. Although Dr. Gofman used similar mathematical calculations as those used by Dr. Goldman, he managed to delete the term "probability" from his analysis, through a remarkable exercise in semantic legerdemain, so that the issue was framed

in terms of the "fraction of causation to be assigned to radiation." In a paragraph adopted in toto by the Appeals Board, Dr Gofman explained:

> It is not correct to ask the question, "was this particular case caused by radiation, or was it not?" Since in any particular case, we can only know the total causal factors, spontaneous plus known carcinogens, the only correct approach is to assign fractional causations to spontaneous and to known carcinogens, if such exist in the history of the individual. Mr. Hughes was definitely exposed to ionizing radiation in the course of his employment at Livermore Lawrence (sic) National Laboratory. Therefore we must assign some fractional causation of his malignant lymphoma and death thereof to the ionizing radiation exposure received. The only question is what fraction must be so assigned.

In addition, Dr. Gofman took issue with the 8.57 rem cumulative exposure set forth in laboratory records, and testified that in his opinion the film badge readings on which the laboratory records were based were the "absolute minimum" exposure which Mr. Hughes received. Based on this exposure, Dr. Gofman calculated that "at the absolute minimum, we must say that radiation incurred in the course of occupation at Lawrence Laboratory is responsible for 7.8% of the causation of the malignant lymphoma in Mr. Hughes". Dr. Gofman also performed claculations based on the assumption that Mr. Hughes exposures were twice and three times the recorded exposure, and ultimately concluded that "the most medically probable contribution to decedent's death as a result of his radiation exposure was 35.6%." Based on this percentage, Dr. Gofman concluded that Mr Hughes life "was shortened by 4.1 years," as a result of his occupational radiation exposure.

Although the judge who originally heard the evidence accepted the findings of Dr. Goldman, and ruled that "...the radiation exposure claimed herein is so relatively minute as to not fit the definition of proximate cause," the Appeals Board adopted the testimony of Dr. Gofman and reversed the decision. The Appeals Board reasoned as follows:

> If we look for a causal connection between the employment and the injury, such connection need not be the sole cause; it is sufficient if it is a contributory cause... Reasonable probability of industrial causation is all that applicant need prove, and the causal mechanism by which decedent's lymphoma arose need not be proved in detail. * * * In our view, the evidence justifies concluding that it is reasonably probable that applicant's occupational radiation exposure was a contributing cause to his developing lymphoma.

The Board's statement of the applicable law is generally correct. If the employee can establish that his employment contrib-

uted in any way to the development of an illness, the employee should recover. It would not matter whether that contribution was 35%, as estimated Dr. Gofman, or 1%, as estimated by Dr. Goldman, as the Board itself recognized. Dr. Gofman's further statement that Mr. Hughes' life expectancy was reduced by 4.1 years makes it clear, to the extent clarification is necessary, that the Board correctly interpreted Dr. Gofman's testimony.

Thus, through the seemingly innocuous change in terminology from probability of causation to fraction of causation, Dr. Gofman has created a situation, at least in the state of California, in which any claimant with a documented history of radiation exposure, who suffers from a cancer which has been stastically associated with radiation, will be entitled to recover workers compensation benefits. Since current cancer incidence data in the United States suggests that approximately 30% of all Americans will experience cancer during their lifetimes, adoption of the Gofman approach, by other jursidictions, would suggest that nuclear utilities and their insurers, as well as other industries in which employees may be exposed to ionizing radiation, will be paying worker's compensation benefits for cancer to approximately 30% of their employees.

The fourth and final case is Irene H. Allen, et. al. v. the United States of America, Civil Action No. C79-0515 (United States District Court, Central District of Utah, 1984). The Allen case is the lawsuit, mentioned previously, brought by individuals who resided downwind of the Nevada Test Site during the atmospheric nuclear weapons testing, who claimed that they, or deceased family members, contracted cancer as a result of exposure to radioactive fallout from the weapons tests. The case was obviously not an occupational exposure case. It is selected for discussion, however, because the measured and calculated exposures to the downwind residents were not dissimilar from the exposures typically presented in the occupational injury cases, and therefore present similar issues of causation. In addition, because of the number of different types of cancer involved, and the careful and thorough consideration given by the trial judge to these issues, it will undoubtedly be looked to by other courts confronted with these issues.

The Allen case involved over 1,000 individual claimaints. They, or the deceased relatives through whom they were claiming, each had individual medical histories, and were exposed to varying amounts of radiation, under different circumstances, over a number of years. The cases warranted individualized attention, yet it would clearly be impractical to do so. In an effort to resolve common issues of law and fact, and to provide some guidelines for the resolution of other claims, the parties agreed to select a number of "bellweather" cases, which would provide a fair representation of the diseases involved, though not necessarily the conditions of exposure, age of the individual or other relevant factors. At the time the "bellweather" cases were selected, neither the plaintiffs' attnorneys nor the defendants

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had investigated in any appreciable detail the medical records or other individualized information. Thus, although the cases were not selected arbitrarily, neither were they necessarily representative of anything other than the indicated diagnosis.

By the time of trial, there were twenty-four such cases, eight of which involved various forms of leukemia, and sixteen of which involved solid tumors. The calculated internal organ doses ranged from 250 mr, in the case of a woman who had died from ovarian cancer, to 31 rad, in the case of a woman who suffered from thyroid cancer. (With the exception of the thyroid cancer, the next highest dose to an internal organ was 3.7 rad to the kidney. There was also a claim for skin cancer in which the dose to the skin was calculated to be 310 rad.) The plaintiffs, not surprisingly, disputed the governments calculation of the organ doses, primarily through the testimony of Dr. Jon Gofman. With the exception of the thyroid and skin doses, however, even Dr. Gofman's calculations did not result in excessive doses, particularly since the exposures, in most instances, occurred over a number of years. Using Dr. Gofman's figures, the organ doses ranged from 8.1 rad, in the case of a child afflicted with leukemia, to 36.7 rad, which interestingly was the dose he calculated for eight of the twenty four cases, all involving different cancer sites.

The court's opinion on the causation question spans ninety pages, and is worthwhile, and indeed essential, reading for anyone involved in these claims. It is beyond the scope of this paper to summarize the court's reasoning, and to discuss the many authorities cited therein. Accordingly, the following discussion is limited to a description of the causation problem as it manifested itself in the Allen case, the rule which the court established for determining eligibility, and the application of that rule to the twenty four cases pending before it.

From the outset of the case, the trial judge made it clear that he understood the difficulties surrounding the causation issues. Moreover, since the plaintiffs' lawyers had endeavored to include most, if not all, cases of cancer among the people who resided in the downwind area during the time of the tests, and since fallout clearly would not have caused all the cancer in the area, the judge was aware from the outset that if he awarded damages to any plaintiffs, he would be required to pick and choose among them. The all or nothing solution in the typical single claimant case was clearly out of the question.

To begin, the court recognized that direct proof of causation was impossible.

> The intrinsic nature of the alleged injury itself thus restricts the ability of the plaintiffs to demonstrate through evidence a direct cause-in-fact relationship between radiation from any source and their own cancers or leukemias. At least within the scope of our present

knowledge, the injury is not specifically traceable to the asserted cause on an injury by injury basis.

* * * *

This does not, however, end the inquiry. That the courts cannot now peer into the damaged cells of a plaintiff to determine that the cancer or leukemia was radiation-induced does not mean (1) that the damage was not in fact caused by radiation; (2) that the radiation damage involved did not result from the defendant's conduct; or (3) that a satisfactory factual connection can never be established between plaintiff's injury and defendant's conduct for purposes of determining liability. Experience and the evidence in the record indicate that indeed it can.

* * *

Following an exhaustive analysis of a number of tort cases and published workers' compensation decisions, the court set forth the rule by which he intended to determine eligibility among the twenty four plaintiffs:

A remedial framework can certainly be fashioned to meet the circumstances and requirements of the parties and issues not before this court in this action. To that end, this court now holds as follows:

Where a defendant who negligently creates a radiological hazard which puts an identifiable population group at increased risk, and a member of that group develops a biological condition which is consistent with having been caused by the hazard to which he has been negligently subjected, such consistency having been demonstrated by substantial, appropriate, persuasive and connecting factors, a fact finder may reasonably conclude that the hazard caused the condition absent persuasive proof to the contrary offered by the defendant.

In this case, such factors shall include among others: (1) the probability that plaintiff was exposed to ionizing radiation due to nuclear fallout from atmospheric testing at the Nevada Test Site at rates in excess of natural radiation; (2) that plaintiff's injury is of a type consistent with those known to be caused by exposure to radiation; and (3) that plaintiff resided in geographic proximaty to the Nevada Test Site for some time between 1951 and 1962. Other factual connections may include but are not limited to such things as time and extent of exposure to fallout, radiation sensitivity factors such as age or special sensitivities of the afflicted organ or tissue, retroactive internal or external dose estimation by current researchers,

> a latency period consistent with a radiation etiology, or an observed statistical incidence of the alleged injury greater than the expected incidence in the population.

Essentially, the court eliminated the requirement of proving causation in fact, and substituted therefor the requirement of demonstrating a "consistency" between the risk created by the defendant's conduct and the injury suffered by the plaintiff. Where this "consistency" is established, the burden of proof is shifted to the defendant, who then is required to rebut the inference of causation. In explaining these rather radical departures from traditional requirements of proof, the court stated:

> Whether the defendant is ultimately held responsible for an injury which may likely have occurred anyway is inherently a question of policy, not of factual connection or causation.
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> * * * * *
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> In cases where, as here, defendant's duty extends to protection of plaintiff from even the possibility of harm, or where, as here, defendant's wrongful conduct arguably has denied to plaintiff a potential opportunity to avoid serious or lethal injury, analysis using "but for" tests in any form falls far short of the mark.

In short, the judge in much of his opinion speaks in language which would be arguably appropriate for a legislator, whose responsibility to create law, but not for a judge, whose responsibility is to apply existing law to the factual situations before him. The conclusions reached by the judge simply cannot be reconciled with existing legal doctrine.

In addition, even as a legislative of policy decision, the court's opinion is deficient in that it provides no basis for predicting the outcome of future cases. Of the ten cases in which the court awarded damages, four involved children, who died of leukemia, and whose highest estimated cumulative exposures ranged from 8.1 rad to 14.2 rad. Since there was nothing to distinguish these four cases from other childhood leukemia cases, one might predict that the court would be inclined to award compensation in all childhood leukemia cases. While the childhood cases are emotionally compelling, and the result is not surprising, the precedent is a disturbing one in view of the relatively low exposures. The court also awarded damages in the cases of four adults who died of leukemia, and whose highest estimated cumulative exposures were in the range of 18 rads. Again, there is nothing to distinguish these four cases in terms of causation from the numerous other claims involving adult leukemia. Particularily in view of the normal incidence of leuklemia in adults, this decision, if read as an indicating

a disposition to compensate all such claims in the Allen litigation, is profoundly disturbing.

The remaining two cases in which recovery was awarded were aberrational: The first involved thyroid cancer of a woman who was exposed in early childhood and consumed large quantities of dairy milk, which was believed to contain large amounts of radioactive iodine. The second case involved a woman who was exposed during puberty, and died of breast cancer in her early thirties. Thus, the court's opinion offers little, if any guidance, to other claimants in cases involving these two tumors.

In the remaining fourteen cases, all involving solid tumors, the court denied recovery. In a number of instances, the denial was premised on the lack of a demonstrable relationship between the type of tumor and ionizing radiation. In other cases involving these tumors, the court presumably will be disposed to deny recovery as well. In others, however, the decisions may have been based on factors which were idiosyncratic to the particular "bellweather" case. As to the tumors involved in such cases, there is little guidance to other plaintiffs.

In summary, as mentioned earlier, the court decided only twenty-four cases; there are hundreds of claims in the Allen case still outstanding. The court's decision offers little, if any, guidance for those claimants, nor for claimants in future radiation injury cases. Thus, in the largest radiation injury case tried to date, the court was unable to resolve the claims within the confines of the existing law. Its efforts to establish a rational basis for deciding claims, even without regard to traditional limits of judicial authority, failed to establish a rational basis for determining eligibility for compensation in future cases.

III. Conclusion

Notwithstanding an increased number of radiation injury claims pending before workers' compensation boards and courts in the United States, there has been no satisfactory resolution of the problem of proving causation, which is inherent in every occupational injury claim alleging exposure to low level ionizing radiation. The obvious difficulty of the courts and other agencies which must decide these cases, has led them to give undue credence to those scientists and other "expert" witnesses who claim to offer simple, straightforward, and unequivocal opinions on causation, in complete disregard of the scientific evidence. The decisions which have resulted form this situation, have created a body of profoundly disturbing precedent, which compounds the already substantial burdens confronting lawyers involved in these cases.

The CHAIRMAN. Thank you, Mr. Schaffer. We appreciate your testimony. You have raised an awful lot of the issues involved here.

As an attorney who is familiar with these matters and has litigated in this area, do you think that the uncertainties that attend the science of radioepidemiology, and therefore must attend any tables that can now be developed, are sufficiently limited so that probability tables might reasonably be used as the basis for a legal determination of causality in radiogenic cancer cases?

Mr. SCHAFFER. I am more comfortable with that in an administrative or worker's compensation type setting than I am in the tort law, in which we really are trying to answer the question of causation in fact. In worker's compensation setting, in an administrative scheme which is set up to make eligibility determinations in what is legislatively recognized to be a problem, we are, to some extent, engaged in social engineering. I think that as long as we understand what the limitations and the uncertainties are, we can tolerate them, we can deal with them.

As I stated before, I am less comfortable with that in a tort setting, because I think in a tort setting we are attempting to answer factual questions. I just do not know at this point whether the tables have that kind of accuracy.

The CHAIRMAN. There really is a real difference between workmen's compensation hearings and regular tort cases that are brought, I have to acknowledge that. But without some sort of a guide in the manner of Dr. Rall's report, do you think that the courts in tort cases, assuming that they may be utilized there—and I am not sure that is the best way to handle the downwind problems—do you think that the courts can make competent assessments of the evidence that may be presented in radiogenic cancer cases without some sort of scientific guide or guidelines like these tables may represent?

Mr. SCHAFFER. I think the courts can make judgments, but it is very difficult to quantify them. As you know very well, the standard in a tort case is whether it is more probable than not. We equate that to a 51-percent probability.

The CHAIRMAN. You see, I am talking about changing that from a probability of risk standard between 10 and 50 percent.

Mr. SCHAFFER. I have grave problems with that in a tort setting, because I think it creates far more problems than it solves and it creates problems potentially across the board because courts can and will look to these things as precedent in other areas, and there are other areas where causation is a difficult question. As I say, I have less of a problem with that—I still personally have a problem with 10 percent—but I have less of a problem with the probabilistic approach and with putting numbers in the probabilistic approach in a worker's comp setting. We are dealing there in the worker's comp setting with a high volume of cases.

The CHAIRMAN. In the case of the downwind situation, it may be, but we have to use some sort of a modified legal approach that might come close to a workmen's compensation setting. For instance, we have proposed to have a probability of risk ratio between 10 and 50 percent, but we have also proposed a limit to total exposure to liability, because we can in no way be certain who actually contracted cancer as a result of atmospheric fallout. So we

do not want the damages to go beyond that which they should be for those who really contracted cancer. On the other hand, we do not want to fail to recognize that there might be some who might not be compensated if we do not have some reasonable approach to it, and if we use the more-probable-than-not standard tort approach.

Mr. SCHAFFER. I testified when I was with the Government before Congressman Eckhardt's committee. The issue in those hearings was, are the courts an appropriate place to litigate these cases, particularly the cases such as the downwind cases. I think Judge Jenkins' opinion demonstrates it: the courts are not a good place to litigate issues as are presented there. I think an approach similar to that which you have just described is difficult.

The CHAIRMAN. Let me give you an illustration. The only real opportunity we have to do anything this year—and it is fast fading in the last days of this session—may be the Micronesia compact. Now, we are willing to give $150 million in a trust fund for those who suffered from atmospheric testing in the Pacific islands but nothing for people who suffered within our own country. What if we set up a similar trust fund, with a limit of liability but nevertheless a recognition that there are some things that are wrong here? Would not these radioepidemiological tables be of some benefit to us? Not a total benefit—they cannot determine everything—but would they not be of some benefit in helping to resolve those cases within the context and framework and limitation of, say, a trust fund? Would that be an intelligent way to approach this?

Mr. SCHAFFER. I think the tables have a great potential for making eligibility determinations within a context such as that one.

The CHAIRMAN. Then you like that context?

Mr. SCHAFFER. In that context, yes. In the tort context, I have reservations.

The CHAIRMAN. I see you represent the defendants in these matters, and certainly they need representation, as do plaintiffs. You look at it, perhaps, through a defense attorney's eyes, and I respect that. But you have admitted that this may be an intelligent way of approaching this problem. I appreciate that, too, because I think your testimony is going to be very helpful to us as we chat with colleagues in the Senate and see what can be done in this particular area.

Let me just ask you this. Do you see any alternative to what the Rall committee and your own committee have been attempting that might help the courts to ease their current state of confusion over radiation liability? Or do you think this is the best we can do under the circumstances?

Mr. SCHAFFER. I do not see alternatives. I have been looking for them. I think again the problem is more acute. We are going to have more cases, and we are having more cases, with the exception of the *Allen* case, in the occupational setting. No, I am not aware of a better situation. I think the tenor of my remarks, at least what I intended to say, is that the courts and the boards are not doing a good job, in part because the lawyers are not giving them a great deal to work with.

In the context of causation-in-fact, we do not have an answer. In a worker's compensation setting, the question of a work relationship—where, as Dr. Rall said, if you have a large number of people exposed to enough radiation, you can predict there is going to be an impact. I think some guidance is called for in that setting. In the tort setting, a particular injury pointing a finger at a particular defendant, more of a one-on-one situation, as I said, I do not think it would be appropriate. I think it would be more appropriate to leave that up to the courts at this point. I must say that those of us engaged in the defense of these cases are using, not Dr. Rall's tables, but are using the methodology. That is the evidence that some of us, at least, are using to say: No, it is not probable; it is highly improbable.

The CHAIRMAN. Or that it is probable under these circumstances?

Mr. SCHAFFER. Or that in a given situation it is probable. And in those situations, cases have been settled, and the cases are settled based on an analysis of the same kinds of factors which go into the tables: amount of exposure, age, sex, the illness, and this sort of thing.

I guess my concern with the tables is that we should not oversimplify them. We should not create the impression that they are a "cookbook." But I do think, bottom line, that the methodology, once it is subject to peer review, once the fine tuning has been done, holds great promise. In answer to your question, I do not have anything better to propose.

The CHAIRMAN. Finally, after all this time, do you think I am right in continuing to pursue a remedy for those people who lived within the shadow of the Nevada tests? If so, do you think my idea of a trust fund and an administrative remedy is the appropriate way to resolve this problem, rather than a tort remedy?

Mr. SCHAFFER. Let me give you several answers to that, if I might. The trust fund idea is an interesting one. I am not sure that the Micronesia precedent is totally applicable, and it is what I alluded to earlier.

The CHAIRMAN. Well, not in the sense that they have to be identical. Maybe the funds may need to be identical; I do not know. That would depend on my colleagues and everything else. But in the sense that this may be an administrative way of resolving what really are difficult problems, and resolving issues where, in fact, the court has held the Government to have been negligent.

Mr. SCHAFFER. I think that you are correct. If what you are saying is that the way to deal with this problem is some sort of an administrative approach in the context of a trust fund, I would agree with that. The ultimate question, the way you initially phrased it, I do not think I have any standing to answer.

The CHAIRMAN. That is a political question: How can we get this through the Congress, assuming we can. Up until now, we have not had a basis to take it through the Congress in the eyes of some of our colleagues. With these tables developing as one of the aids or tools, there may be a basis for resolving this problem, at least in a reasonable way.

Mr. SCHAFFER. My own feeling is that I do have problems with Judge Jenkins' opinion, though I admire the work that went into

it. Even if the opinion is upheld, I think it does not really solve the problem except as to the 24 cases that it dealt with.

The CHAIRMAN. I agree with you. It creates more problems in the sense that there are no definitive legal guidelines to go by in future cases.

Mr. SCHAFFER. I agree with that.

The CHAIRMAN. I want to thank you, because I think that your testimony has been very straightforward here today. I think you have been helpful to the committee. You certainly have, I think, helped to make a case. Whether or not these tables are subject to criticism, they at least are an appropriate way to go to try and resolve these very difficult problems. Perhaps an administrative resolution of these problems is better than just an ad hoc tort claims approach that sometimes is very just and sometimes very unjust. I want to thank you for being here. We appreciate your being with us today.

Mr. SCHAFFER. Thank you.

The CHAIRMAN. We will excuse you because I know you have a heavy schedule. We will be happy to receive into the record any additional comments you might have after these questions. I will be happy, if you have any additional comments or additional information you would like to submit to us.

Mr. SCHAFFER. Thank you very much.

The CHAIRMAN. Thank you very much, Mr. Schaffer. We appreciate your being here.

Mr. Jablon, we will now turn to you. You have been a steady devoted witness before this committee. We appreciate it, and I think you have added a great deal to our knowledge through the years. We look forward to taking your testimony now.

STATEMENT OF SEYMOUR JABLON, DIRECTOR OF MEDICAL FOLLOWUP AGENCY, NATIONAL RESEARCH COUNCIL, NATIONAL ACADEMY OF SCIENCES

Mr. JABLON. Thank you, Mr. Chairman. My name is Seymour Jablon. I am a biostatistician. I am on the staff of the National Research Council, where I am responsible for the Council's participation in the work of the Radiation Effects Research Foundation in Hiroshima and Nagasaki, Japan. I have myself spent 6 years in residence in Hiroshima, studying the late effects of radiation on the Japanese survivors of the atomic bombings. You may be interested to know, Mr. Chairman, also that I am a member of the Dose Assessment Advisory Group, which is a Department of Energy committee with oversight over the efforts that are being made to establish doses for the offsite residents around the Nevada test site. I am a member of the National Council on Radiation Protection & Measurements, which is a not-for-profit corporation chartered by the U.S. Congress in 1964, among other things to advise on radiation protection practices. I am also a member of the NIH ad hoc working group, which is chaired by Dr. Rall, but I am testifying today primarily on behalf of Scientific Committee 71 of the NCRP.

As you are aware, Scientific Committee 71 on radiation exposure and potentially related injury, under the chairmanship of Victor P. Bond, has been evaluating the probability of causation methodolo-

gy for determining the probability that an individual's cancer is causally related to his or her previous radiation exposure. Both Dr. Bond and I have testified before this committee on this subject during earlier hearings. Because Dr. Bond is out of the country at this time, I have been asked to provide you an update on his committee's current thinking regarding the probability of causation method. The remarks that I will make are my own and, therefore, may not necessarily represent the unanimous opinion of the members of Scientific Committee 71, nor do they represent the policy of the NCRP or of the National Research Council.

The initial purpose of the Scientific Committee 71 report was to provide information on the value, use, limitations, and method of calculation of probability of causation. In 1983, section 7 of the Orphan Drug Act mandated an ad hoc working group under the National Institutes of Health to prepare radioepidemiological tables, which is the subject of today's hearings. Because of the NIH working group's effort, the NCRP committee decided that probability of causation tables or data for calculations would no longer be needed in the NCRP report. There has been a close liaison between the NCRP and the NIH group, and there are no conflicts in the activities of these groups.

By the fall of 1983, an initial draft NCRP report was sent to 10 critical reviewers for their comments on its concept and technical accuracy. The response on the concept was not unanimous. However, the majority of the reviewers were favorable in their comments on the use of this calculation method in assessing causation. Some persons have reservations because the radiation risks derived from studies on populations apply to a statistically average person. Others are concerned because radiation probability of causation will be calculated with little or no knowledge of the cancer risks posed by other agents such as chemicals.

In fact, not enough is known about these other risks, with the single exception of cigarette smoking, to take them into account.

Despite such objections, the method is considered by Scientific Committee 71 to be an acceptable scientific method that applies available knowledge to the estimation of the probability that an individual's cancer was caused by his or her previous radiation exposure. One of the concerns beyond the scientific issues is the manner in which the estimate of probability of causation will be applied in legal and administrative decisions. The committee has included in its draft report a chapter on the legal framework in the United States into which such estimates of probability of causation might be introduced. The concept of probabilities is not new to law, but it is not known how the probability of causation estimates would be used for burden of proof, in either tort cases or worker's compensation cases. Another problem in legal applications is the fundamental policy decision as to the appropriate level of probability at which to set compensation. Scientific Committee 71 considers this to be a social judgment which they will not address in their report.

There will be a chapter that explains the mathematical basis for calculating probability of causation. This explanation, as well as the entire report, is being written for all persons interested in this methodology. It is hoped it will be useful to many professional disciplines, including physicians, lawyers, judges, and others. It will

not contain risk coefficients or tables from which actual calculations are made. In this way, the NCRP and NIH group reports will be complementary.

The report will discuss the relevant radiobiology on which the probability of causation is based. The key to this discussion is the evidence supporting the current assumption that there is no threshold dose of radiation required to initiate cancer. This is important since the probability of causation calculation is based on risk coefficients derived mostly after high radiation doses and an interpolation is necessary to estimate risk at low doses.

The report will recognize that the calculation of the probability of causation rests heavily on knowing the radiation dose received by the individual or organ of concern. If the dose information is incorrect, the resulting calculation will be equally in error. Therefore, a chapter is devoted to explaining radiation dosimetry as it may affect the calculation of a probability of causation.

The work of Scientific Committee 71 of the NCRP is moving forward. Several chapters are being rewritten at the present time. As soon as the next draft is assembled, we expect it to be sent to the 75 members of the NCRP for their review. This will probably occur about the end of 1984 or early in 1985. Thus, we might expect the final report to be published later in 1985.

Senator Hatch, we appreciate the efforts that you, other members of your committee, and members of your staff have made to achieve a rational approach to the difficult issue involved in compensation claims for alleged radiation injury. I am pleased to have had this opportunity to appear before you to provide this short brief on the status of Scientific Committee 71 of the NCRP. I would be happy to respond to any questions you may have.

The CHAIRMAN. Thank you so much, Mr. Jablon. I want to thank both of you. You do not have a draft report available at this time, I take it?

Mr. JABLON. No.

The CHAIRMAN. But we do have the draft report of Dr. Rall's Ad Hoc Working Group, which is quite extensive. I am losing my eyesight on this one issue alone, with the reading material we have. You have 320 pages in this draft report.

Dr. Rall, I hope you realize that you are about to enter into a vortex of controversy. Now, I did not mean to do this to you, but I think we can agree that your committee's work is of great interest and importance to this country, and not just in the case of the downwinders or in the case of the atmospheric testing.

I declined a number of requests from people to testify concerning the scientific merits of your work because, considering how difficult your task has been, I thought it only fair that you be allowed to present your position first, to file your report before people take issue with it at a congressional hearing. Of course, this is a draft report. Can you tell us about when you expect to have the final report printed and out?

Dr. RALL. We expect to eceive from the National Academy of Sciences' Oversight Committee their final review of our report sometime at the end of October or the first of November. We will meanwhile be working on revising the third draft which you now have

and expanding the tables. We would hope to get a report to the secretary by the middle of November.

The CHAIRMAN. In this draft report, you do not have any radioepidemiological tables?

Dr. RALL. We have tables that Dr. Land prepared last night, some 50-odd pages of them.

The CHAIRMAN. We can have that for the committee, or is it too preliminary to give those to us.

Dr. RALL. You can have them as a freedom-of-information request because they are available.

The CHAIRMAN. We would hope we would get them without asserting our rights.

Later, when your report has been available for a few months and appropriate comments can be made, I would just mention that more extensive hearings will be in order, where we will bring in those who will be critical and those who will be supportive of the report. On the other hand, since the legitimacy of your committee has already been challenged, it is only fair, it seems to me, that you have the opportunity to respond, at least in this preliminary draft report context, and we will give you another opportunity, once the report is finalized.

A conference was conducted in my home State of Utah yesterday, at which Dr. Ernest Sternglass, Dr. Alice Stewart, Dr. Carl Morgan, Dr. Thomas Mancuso, and Dr. Linus Pauling charged that your committee is biased, that it represents a Government interest, and that your members have testified against radiation victims, and that being pronuclear, your members underestimate the risk of radiation exposure. Let me give you a chance to respond to those claims.

More importantly, do you think that your committee represents the preponderance of scientific opinion regarding the science in question that we have asked you to consider in these matters.

Dr. RALL. I think so. When the committee was constituted, there were extensive discussions with Dr. Brandt the Assistant Secretary for Health; Dr. Wyngaarden, Director of NIH, and other people to try and get the broadest possible participation of people with expertise in statistics, in cancer, in epidemiology, and to try and avoid extremists on either side of the question who seemed to have a vested point of view that they would attempt to support with data. We felt that it was more important to have people who have no vested interest in what the tables really ended up showing but who were trying, insofar as possible, to make calculations on the basis of existing data.

The CHAIRMAN. We also have three groups looking at this as well, and they all three are going to have to be pretty much in agreement for those tables to be worth anything. As I understand it, we talk in terms of your committee, the Rall committee or the Ad Hoc Working Group, to develop radioepidemiological tables, but we also have the NCRP Committee 71, which Dr. Jablon has mentioned, which is the National Council for Radiation Protection and Measurement, and, of course, you have the National Academy of Sciences' Oversight Committee.

So it is not as if you on your committee have to make these final determinations. All of these committees have to come together with regard to the final report; is that correct?

Dr. RALL. That is correct. In addition, several of our draft documents have been moderately widely circulated and we have had comments from a variety of Federal agencies and from a variety of outside bodies. So we have benefited from quite a bit of input, in addition to the two extra committees you mentioned.

The CHAIRMAN. You mentioned in your earlier statement that these committees are trying to stay away from the two extremes, those who are so pronuclear that they find no liability or anything wrong with anything the nuclear industry does or anything pertaining to nuclear power, including atmospheric tests. Then you have the other extreme, who cannot find anything right with what the nuclear industry does.

Dr. Rall, Public Law 97-414 charges the Department of Health and Human Services to develop these radioepidemiological tables. Congress stipulated HHS because it is the only department with the scientific competence that is clearly free of any special interest in this matter. At least, that was our thinking at the time. You say in your written testimony that your report is being reviewed by an interagency committee as well; is that correct?

Dr. RALL. Yes; that is correct.

The CHAIRMAN. That is interagency of Health and Human Services?

Dr. RALL. No; the Office of Science and Technology is organizing the critique.

The CHAIRMAN. Presumably, that committee is comprised of people from the Departments of Energy, Defense, Justice, and so forth.

Dr. RALL. Yes, sir.

The CHAIRMAN. So, it involves all agencies of the Government, or at least the critical agencies of the Government that might have something to do with this. So they are also overlooking your work; is that correct?

Dr. RALL. That is correct.

The CHAIRMAN. You also say that when the review is completed, appropriate changes will be made in the report?

Dr. RALL. Yes.

The CHAIRMAN. I presume you mean that.

Dr. RALL. Yes, indeed. We sometimes have been accused of representing a moving target because of the continuing changes we are making in the report. The second draft, for example, differed quite markedly from our original fundamental-assumptions draft of last November, and our third draft incorporates considerable changes over the second draft of July.

The CHAIRMAN. Congress intended, and the law does require the Department of Health and Human Services and this Department alone to supervise the development of the tables, however?

Dr. RALL. Yes.

The CHAIRMAN. We were concerned because we wanted the most efficient, the most scientific, the most fair and equitable agency to handle this matter, and we felt that would be the way to do it. Plus, I also wanted an agency that I overview.

Dr. RALL. Thank you. However, it is true that other agencies of the Government have individuals in them who possess special expertise and special knowledge in some areas. So without there being necessarily any vested interest, there might be expertise that would be helpful to this committee, and we would appreciate that input.

The CHAIRMAN. Does the panel believe that the formulas and the tables you have developed are good enough to provide a reasonable means for assessing claims? For example, a report by the Arthur D. Little Co. states that a lottery would be just as good as what you have produced. Is that so?

Dr. RALL. We do not agree with the report prepared by Arthur D. Little. We have examined it in some detail; it has been available to us for some months. They make several statements which we find unsupported, logically or by fact.

A major point of theirs is that tables of the probability of causation require that the causes of cancer be mutually exclusive for one to calculate a table of probability of causation for radiation as a cause of cancer. We are unable to see any foundation for that statement, and this represents their major criticism. So, we find it not useful. We also worry that they did not consider the interactive effects of different potential carcinogenic agents, and these can be defined as multiplicative effects or additive effects or subadditive effects.

We have considered this in considerable detail. Data are only available for smoking and lung cancer, as it is related to radiation. We have prepared, actually, tables categorizing individuals into eight different groups on the basis of their smoking history. We can make some sensible, we think, calculations about the probabilities of causation from radiation, depending on whether one is a past smoker who smokes small, medium, or large amounts. However, for all of the other possible carcinogenic agents or genetic things, there are no data available. So, it is not possible to break this down any further;

We felt that the Arthur D. Little report had not really even gone into any detail about the interactive effect.

The CHAIRMAN. Fine. But would these be good enough for the law to resolve these problems?

Dr. RALL. More or less. I was interested in what Mr. Schaffer had to say, because he seemed to feel that the tables would not be accurate enough to be useful in tort law.

The CHAIRMAN. No; that was not what he was saying. He was afraid of the unlimited exposure that tort law would give, based upon scientific tables. So he was concerned about the implications of tables with regard to tort law and the unlimited nature of each case standing on its own and each case filled with various facets, such as emotion and so forth. He did not quite say that, but I took it that way. You are dealing with individual cases. You are not dealing with a vast panorama of problems that really do need to be solved in the most fair way possible, which is what we're trying to do.

Dr. RALL. I could say that we have an entire chapter which Dr. Beebee is largely responsible for on the uncertainties associated with the tables. We feel that, in general, the tables will be most

useful at the extremes, where there are probabilities of causation that turn out to be on the order of a few percent or less than 1 percent. I think under those circumstances, one could say that the chances that that individual's cancer was due to his radiation history is extremely unlikely. There are other instances where the probabilities are well in excess of 60 or 70 percent. I think in situations like that, one could be sure there is really a high likelihood that the cancer was really radiation related.

The problem probably arises most seriously in 20, 30, 40, 50 percent calculations, where the chances that the 30 percent is accurate is not particularly high. I think all you can say there is, there is a considerably better than zero chance, and there is by no means a conclusive chance.

The CHAIRMAN. As the panel knows, the law requires actual tables of probability. This was required so that people who are not experts can see the general variation in the relationship between radiation and cancer in terms of a number of factors. I do not doubt that the importance of the better than 300-page text of the report is important. I do not doubt that it is important. In fact, I think it is extremely important. But I wonder what we can expect to see in the way of intelligible tables. You worked on those last evening, and we will have at least your preliminary set. So, we would like to have those at the end of the hearing, if we can.

I am looking for something that will give the average plaintiff, the average defendant, and their average attorneys—although that may be a contradiction in terms—some sense of proportion in assessing a claim. What is the panel intending to do to further this end?

Dr. RALL. We may be giving you more than you want because we're giving you some rather brief tables from which you can calculate the probability of causation for any cancer and any radiation dose or any sum of radiation doses. But you must do some multiplication.

We are then providing you some graphs, so that you can see visually, with exposures of 1, 10, and 100 rads, what the probability of causation will be as a function of age. We will finally be giving you tables for the probability of causation with each cancer, and in the case of lung cancer, with respect to the smoking history, and subdivided according to sex, and subdivided according to age at exposure and for exposure to 1, 10, and 100 rads. These will take up some 50-odd pages.

If we were to subdivide this into 1-rad exposures and age at exposure 1 to 70 years, we would end up with something on the order of 15,000 pages, and we thought you, perhaps, would not find that useful. So we are attempting steer between Scylla and Charibdis and not give you more than you want and yet give you enough so that they will be useful.

The CHAIRMAN. Does the panel feel that it did the best job it could, or were you hampered by the time constraints or financial constraints that we put in the bill. I was surprised to see that HHS did less than $100,000 to this effort, which is a pretty small amount when you consider the vast amount of effort that had to be made. Now, whatever may come of your work, it was something of a bargain in Federal terms or in anybody else's terms, considering gen-

erally what Federal studies actually cost. Do you think there should be some regular organization or office to continue with future editions of the tables? And if you do, how do you think the future efforts should be organized, and should there be a line-item authorization for this?

Dr. RALL. We have discussed this, and we think it would be useful to have a standing committee for two reasons. One, if a new committee is established after this committee has submitted its report, it would then be under much less of a time constraint. It should be so organized that it would have liaison with the BEIR IV Committee, which is in the process of organization right now by the National Academy of Sciences. We also felt that it should be a somewhat larger committee.

There are two aspects from the standpoint of timing that we have considered. One is that there may at any time come out a new publication or a new series of publications which would warrant revising one portion of the current report, such as dealing with perhaps one single cancer or one age group. So a revision should be made when any really significant change comes, even affecting one.

We then looked rather carefully at the recalculation of the doses received by the Japanese in Hiroshima and Nagasaki. That dose recalculation will probably be available in another year or year and a half, but it will then take another year for it to be applied individually, case by case. Then we expect——

The CHAIRMAN. That should be very helpful.

Dr. RALL. It will be extremely helpful.

The CHAIRMAN. It is important to do this work and continue to do this work.

Dr. RALL. The other thing is that the Japanese experience investigating the individuals up through 1982 should probably be available in 1986 or 1987, with the new dose calculations. So about that time, it would be useful for a general review of the tables.

The CHAIRMAN. Dr. Rall, in your written testimony you stated:

> No court should consider the tables reliable evidence that a specific individual's cancer was caused by radiation.

On the other hand, the following statement is found in the conclusion of your draft report:

> Although the sources of uncertainty are numerous, and although its degree at the level of the individual is not only considerable but cannot be measured, the procedures for estimating PC's described here should reduce the general level of uncertainty that inevitably surrounds any individual claim as to the role of radiation and the etiology of that cancer by bringing to bear on the individual case the extensive knowledge of risk that has been accumulated for four decades.

What is meant by these two statements? If the courts do not rely on the tables in individual cases, upon what should they rely then?

Dr. RALL. I think we overstepped our bounds in suggesting what the courts should or should not rely on. I think the second statement, which is somewhat more circumspect, which suggests that although there are uncertainties to varying extents, depending on the cancer and depending on the dose, nonetheless, we are reasonably confident that these represent the best that one can do from a scientific standpoint at this time.

The CHAIRMAN. I presume you will make the final changes then in the final draft?

Dr. RALL. We are, Senator, a moving target, and we are continually revising.

The CHAIRMAN. Some of these other groups may not be nearly as tough as I might be. I just want you to know.

Last March, the Arthur D. Little Co. published a report that was sponsored by the American Nuclear Insurers. Their report was entitled, "A Critical Review," which is something of an understatement as we look at it. Considering that Mr. Marrone is here this morning on behalf of the American Nuclear Insurers, I would like to ask the panel what it thinks of the criticisms in that report. You have mentioned some of your feelings. Particularly, I am interested in your response to the claim that the probabilities cannot be credible because there are multiple causes for cancer, and these causes interact in ways and to a degree that have not yet been determined. Now, you have addressed that to a degree, but if you can be more specific, that would help. Feel free at any time, Dr. Jablon, to add what you would care to add.

Mr. JABLON. I have read the various versions of the Arthur D. Little report, and I have written to Mr. Marrone about it. I really cannot quite understand the attitude of the authors of that report. They have focused extensively on the issue of whether causes are independent or not independent. They are defining probability of causation in a way which is different from the way in which we define it. The question of how you define it has social implications.

Arthur D. Little says, here is a particular cancer occurring in a particular person who has various characteristics and a certain radiation dose. Now they want to apportion the probability among all of the various causes that might apply: so much was due to cigarette smoking, so much to radiation, so much to benzyne, and so forth. Our approach is different. It is what mathematicians call a conditional approach.

We assume that if you are interested in judging whether radiation has harmed a person, you take that person as he is. This person happens to be a cigarette smoker. He had a radiation dose. He develops a lung cancer at some later time. The question we are asking is not, what is the probability that the cigarette smoking caused the cancer? The question we asked it this: Given that he was a cigarette smoker, by how much was his risk of lung cancer increased by the radiation dose. That is it in essence.

This difference of approach obviously would create a large difference in outcome. I do not know why the authors of the Little report have steadfastly declined to accept the notion of a conditional probability of causation, accepting individuals as they are.

The CHAIRMAN. Do you have anything to add, Dr. Rall?

Dr. RALL. No, I do not.

The CHAIRMAN. Or anybody else? Please feel free, any of you, to respond to these questions.

Would the panel please comment on whether it believed these tables would lead to an epidemic of successful claims against the nuclear industry and against the medical profession. What if the cutoff for successful cases is the 50-percent probability of causation,

and what if this cutoff is 10 percent? Can you answer those three questions?

Dr. RALL. I think Seymour Jablon has made some calculations about that, and you can see something roughly by looking at the tables themselves.

Mr. JABLON. I think if a cutoff were set at 50 percent, very few claimants indeed would ever be able to collect anything. Very few would establish a valid claim. Very few cases would qualify.

The CHAIRMAN. Based upon the radioepidemiological tables you now have developed?

Mr. JABLON. Based upon the radioepidemiological tables. The fact is that radiation does cause cancer, but the rate at which it causes it is not large, particularly following small doses. If the probability of causation were set at 10 percent, then some claims would be accepted.

I ran a calculation at one point because I was interested in the question of what would the social effect be? What I did was to assume a population of 1,000 men aged 20 who worked for the next 21 years, that is through age 40—who received a mean dose to the marrow of 26 rads over a 21-year working history. Now that is a big dose. I will not say that no nuclear worker ever gets a marrow dose that large, but very few do.

Leukemia, as you know, is the most radiogenic cancer there is. The probabilities of causation for leukemia are generally higher than for anything else. The calculation shows that these 1,000 men, over their remaining lifetimes at U.S. rates, would generate a little over 6 cases of leukemia. They would also generate about one-and-a-half excess cases of leukemia as a result of the radiation. If the PC were set at 10 percent for paying claims, approximately four, if I recall correctly, of all of the leukemias would be awarded compensation; 90 percent of them would be the radiation-induced cases and about half of them the non-radiation-induced cases. The way that would work is because of the age distribution of the radiation-induced and the non-radiation-induced would be somewhat different, so you could distinguish on that basis.

This convinced me of two things. No. 1, the cost to any industry which had reasonable precautions concerning radiation exposure to its workers would not be excessive; but second, the very fact that a compensation scheme was predictable and based upon certain dose levels would impel employers to ensure that doses to their workers would be below amounts which would be costly to them. So there would be this indirect beneficial effect.

The CHAIRMAN. Is the probabilistic method that you have developed applicable to toxins other than radiation?

Mr. JABLON. In principle, yes: in practice, no. The difficulty is that for other toxic torts, so called, we do not have risk estimates based upon the dose, and we do not even have doses. We know that benzene, for example, causes leukemia. We do not know how much benzene causes how much leukemia, and we do not know how much benzene exposure any particular worker had. So you do not have the ingredients. The same is even true of asbestosis and mesothelioma. We know that asbestos causes mesothelioma. There is no way of calculating a dose, and there is no way of knowing how much asbestos exposure causes how much mesothelioma.

The CHAIRMAN. Then what would you say to people who say that radioepidemiological tables would be a precedent for toxins such as benzene or dioxin or, in the case of asbestos, the causation for asbestosis.

Mr. JABLON. I say to them, they are wrong; that the basis for doing this for other toxic torts simply does not exist, nor will it exist in the foreseeable future.

The CHAIRMAN. Do you gentlemen believe that there are many cancer victims who have received doses that are acceptable under current safety standards and who have probabilities of causations in terms of your tables in excess of 50 percent? Do you believe there are many?

Mr. JABLON. If you had said 20 percent, I could answer it easily. I do not know about 50. There would be workers whose PC's could be——

The CHAIRMAN. What about 20 percent?

Mr. JABLON. You are pushing me to the wall, Senator.

The CHAIRMAN. I am. That is what I am doing.

Mr. JABLON. I really do not know. It is conceivable because the standards involve doses of 5 rem a year. Now, if you had somebody who was getting 5 rem a year for 30 years in a row—I do not know if there is such a person, but if he did and he got leukemia, he would have a pretty high PC.

Dr. RALL. Charles may be able to answer that, after looking over the tables he prepared. The question is, Could someone receiving a permissible dose of radiation because of his occupation, after 25 years of receiving what was really a permissible dose, then have a probability of causation of any cancer which was in excess of 50 percent?

Mr. LAND. Yes, I would think that might be true. If you took the chronic granular leukocytic leukemia, it seems to be the one where you get the highest PC's. There is a graph on page 163, which gives a PC for a person exposed to 10 rads at age 20. If the leukemia occurred about 5 years later, the PC would be over 50 percent. So if you take somebody who is exposed to, say, 15 rads in 3 years, there would be a portion of the curve that would go over 50 percent.

The CHAIRMAN. Do you gentlemen think that the method and tables you have produced are superior to what the Veterans' Administration is now using to assess the claims of atomic veterans?

Dr. RALL. I am not familiar enough with what the Veterans' Administration has done, although I have seen in Mr. Schaffer's speech an analysis of some of the decisions in the veterans' cases which he felt were illogical. Perhaps Seymour Jablon is aware of the VA tables.

Mr. JABLON. The VA does not have tables. The VA operates, as you know, on a presumption that the veteran will be given the benefit of the doubt.

The CHAIRMAN. I had not noticed that with regard to their cases.

Mr. JABLON. That is the law.

The CHAIRMAN. I understand, but I had not noticed that was the way they worked in practice.

Mr. JABLON. The question is, How much of a doubt and how much benefit? I have looked at cases decided by the Board of Veterans Appeals in which you can calculate a PC. It turns out to be

one-half percent or something like that, and the Board says: "Well, it's possible, and so we'll make an award." I think the Veterans' Administration very badly needs some kind of a roadmap to let them know where they are: Are they in Utah or are they in New York; they really do not know at this time. The members of the board are usually not persons who are well informed about radiation carcinogenesis and they need help.

The CHAIRMAN. So this would be helpful to them to prevent injustices that many people feel are occurring in these matters.

Mr. JABLON. I would think it would be helpful to them.

The CHAIRMAN. I asked you the question with regard to cancer victims who have received doses acceptable under current safety standards but over a period of time that might have probability of causation, in terms of your tables, in excess of 50 percent. I asked about 20 percent and so on. Do you think that your tables will have much effect upon radiation safety standards?

Dr. RALL. I would think they would have a certain effect. I think, though, it is important when you look at the tables and see high probabilities of causation, frequently the high probabilities of causation involve a cancer that at that age group is quite uncommon. So with chronic myelogenous leukemia in children, the probabilities of causation become quite high, but this is an extraordinarily rare cancer in children. So the total number of children that get it is so small, we're talking about almost nothing in the way of numbers.

It certainly is true, were I running a company in which some of the workers received radiation, I would look at the tables very carefully and adjust my standards to minimize the liabilities I might incur.

The CHAIRMAN. One last question. You are going to have a number of critics on both sides of this issue who will say you have been too conservative in your probability of causation estimates and in your radioepidemiological tables determinations, and others will say you have been too liberal. If you were to characterize where you feel you fall between those two extremes, where would you say?

Dr. RALL. I suppose somewhere in the middle. I suppose we are a little more comfortable if we are shot at in both directions rather than in just one direction. If only the pronuclear people complained, we would worry that we were too far on one side. So I think we would feel more comfortable if we were attacked by both sides.

The CHAIRMAN. Likewise, I take it, if only the antinuclear people complained, you would be concerned about that as well?

Dr. RALL. Yes, we certainly would.

The CHAIRMAN. Do you feel that these tables you have developed and the report that you feel you will be able to issue within a short period of time represent the mainstream scientific thinking in this country?

Dr. RALL. That is my opinion, and I suspect the fact that we are in substantial agreement with the NCRP committee and more or less in agreement with the National Academy Oversight Committee, and that suggests that we are probably in the mainstream.

The CHAIRMAN. I want to thank each of you for being here. We will have additional questions for you, after we have had a greater opportunity to digest the report and look at the tables and, of course, hear the criticisms that are bound to come. We appreciate how difficult your problems are, and we also appreciate the work that you have done, at least as far as we understand it in your testimony here today. We certainly will look forward to hearing the criticisms and the plaudits that people may or may not give as we go into the future on this matter. I want to thank each of you. I know that you are trying to do the best that you can, and that is what is important here. Thank you so much for being with us.

Before I call our second panel, let us take about a 2-minute break so that our reporter can have a second or 2, and then we will reconvene.

[Recess taken.]

The CHAIRMAN. This has been an extremely interesting hearing to me, and I imagine it is going to get more interesting now with this second panel. I would like to welcome our second panel, Mr. Joseph Marrone, who is vice president and general counsel of the American Nuclear Insurers, Mr. George Gleason, who is executive vice president and general counsel of the American Nuclear Energy Council, and their associates which I will ask them to introduce.

As with the previous panel, of course, I ask you to summarize your formal statements because I am pressured for time so that we can have more time for discussion. I will put the complete statements in the record. I do want to give you as much time as I can. I am pleased to see you here this morning, and I want to express that this committee is most interested in what the insurance and nuclear industries think about this project and how you think the tables should be used, or not be used, whichever is the case.

Mr. Marrone, we will begin with you.

Mr. MARRONE. Mr. Chairman, I am Joseph Marrone, American Nuclear Insurers. Our prepared statement today is made on behalf of not just the nuclear insurers but several trade insurance organizations representing the insurance industry generally. Mr. Schmalz is spokesman on behalf of the insurers and has a prepared statement, and Mr. Schmalz is our chief witness.

The CHAIRMAN. Thank you. Mr. Schmalz, we will turn the time over to you.

STATEMENT OF RICHARD SCHMALZ, ATTORNEY AT LAW, ON BEHALF OF AMERICAN NUCLEAR INSURERS [ANI], MUTUAL ATOMIC ENERGY LIABILITY UNDERWRITERS [MAELU], NATIONAL ASSOCIATION OF INDEPENDENT INSURERS [NAII], ALLIANCE OF AMERICAN INSURERS [AAI], AND AMERICAN INSURANCE ASSOCIATION [AIA]; JOSEPH MARRONE, VICE PRESIDENT AND GENERAL COUNSEL, ANI; MARGUERITE SHEA, ASSISTANT MANAGER, MAELU; AND JOSEPH FIKSEL, MANAGER, DECISION AND RISK MANAGEMENT UNIT, ARTHUR D. LITTLE, INC.

Mr. SCHMALZ. Thank you very much, Mr. Chairman.

As the first page of our statement indicates, we are speaking today not only on behalf of the two nuclear pools, American Nucle-

ar Insurers and Mutual Atomic Energy Liability Underwriters, but also for the National Association of Independent Insurers, the Alliance of American Insurers, and the American Insurance Association. The two pools themselves have about 300 members who are engaged in writing property and casualty insurance on nuclear risks. The three trade associations have among them approximately 850 members for whom general liability insurance and workers' compensation insurance forms an important part of their own business.

It is for this reason that we share a deep interest in any proposal that could substantially change the ground rules for awarding damages under the tort system or compensation. It is to be remembered that under these systems, the funding for the claims is solely from private funds, and this has always carried with it an implication that there be a strong causal connection between the activities of these businesses and the injuries. As I am sure we all know, there has been tremendous pressure to expand the scope of these privately funded compensation system and to increase not only the number of claims that they compensate, but the amounts of compensation.

The CHAIRMAN. You are concerned with after-the-fact liability that you had not contemplated when you set up the insurance programs to begin with?

Mr. SCHMALZ. Yes; and it is even more fundamental than that. It is not just a matter of our own rating, which is bad enough, but it is unpredictable for the industries themselves, and it can lead to really uncontrollable cost if we build in an automatic system that substantially departs from the ground rules.

The CHAIRMAN. I take it, you agree with Mr. Schaffer that if you use the probability-of-causation approach, it would not be appropriate for regular tort cases, but it may be appropriate under an administrative context?

Mr. SCHMALZ. We have thought about that, and we appreciate the distinction. We do agree with Mr. Schaffer. We have a little bit more concern than he has with respect to workers' compensation insurance. It is true that it has social insurance aspects to it, and it is true that it does not have exactly the same standard of causation that the tort system has, but it's still important to remember that there needs to be some rational connection between the employment and the injury before you can justifiably award compensation.

We have had experience with black lung, where the eligibility was greatly increased, and they tend to get out of control because they are administrative, automatic systems. So we do have a little more concern than Mr. Schaffer expressed with respect to the workers' compensation system.

But in a nutshell, Senator, we appreciate very much as insurers the desirability of introducing more predictability, and we use well-conceived probability estimates throughout our business in sound underwriting, setting rates for classes, and setting rates for even individuals. But it was perhaps our concern about the use of group statistics in our own business—we rely heavily on group statistics—to do this. Our familiarity with probabilities led us to have an

intuitive feeling that trying to pick out and assess a probability of causation for an individual was, perhaps, too much of a task.

We have immense volumes of statistics, and yet we ourselves are not able to do that with very much confidence. Perhaps one simple example from insurance rating practice will illustrate what I mean. Automobile insurance rates are based on a system of group classifications. We have enormous experience which shows on an average what the expected losses of these folks are. Yet these rates, with all of this experience behind them, are often criticized as not truly representing the loss potential of any individual driver. So the criticism goes, it would be ideal if we could develop a system that would allow us to pinpoint an individual driver and say just what his true loss potential was. There are millions of accidents, so the criticism goes, so it must be relatively easy to do this.

Unfortunately, it is not. We have had people look into it. They say that for collision insurance, for example, it would take 50 years of watching an individual driver's experience to come within a 70-percent chance of being within 30 percent of the true value of that individual's loss experience. Contrast this with the picture that we are dealing with here, trying to pinpoint a chance of a cancer being caused by a specific dose of radiation on very scanty data, and you will see what was the cause of our concern.

It was this intuitive uneasiness about the probability of causation that led us to believe that a thorough analysis was important. We consulted with our own actuaries and they confirmed it and they recommended an independent analysis and we engaged Arthur D. Little to do that analysis for us, and Dr. Fiksel is here with us today to testify in that regard.

I do not want to anticipate his testimony. I merely want to say that it confirms the uneasiness that we have, and we just do not believe that these tables, in the present state of knowledge, would be sound and useful as a means of determining eligibility for compensation, either under the tort system or the worker's compensation system.

We noted that in the remarks made this morning, in the draft report, the authors addressed this probability of causation problem. I am just quoting here from the draft report, and I realize it is only a draft report, and it is an earlier version, and it is subject to revision. But it says:

> Attempts to estimate probability that an observed effect resulted from one of several causes are not uncommon, even in the more exact physical sciences. Decay of short-lived exotic particles in physics where only a small number of events can be observed, and several potential mechanisms exist, is in some respects analogous to the problems involved in constructing radioepidemiological tables.
>
> In both cases, probabilities are calculated from a small number of events. There is, however, an important difference. In physics, there is a large number of well-tested comprehensive theories to guide one's calculations; whereas in biology and medicine, there are almost no well-established general and predictive theories.

We think there is also another very important difference, from a pragmatic viewpoint. When a new scientific theory is applied to physical applications, its usefulness can usually soon be tested and evaluated without seriously disrupting practical activity of incurring great financial risk. But when a new scientific theory or model is applied on a broad scale to a matter such as awarding compensation to injured persons at the expense of private individuals or

firms, there may be a substantial financial impact. Not only is it impossible to verify the model by the results, but it is difficult to mitigate or reverse its effects should the invalidity of the model become clear.

We feel that the radio epidemiological tables that are now being prepared may have just such a substantial impact on the insurance that the pools provide at the 87 nuclear powerplants that they now insure. The total amount that the insurers have at risk is about $9 billion, with a limit of $190 million at each location. Our pool's concern is not so much from the claims from the members of the public; we believe the public is well protected from exposure to nuclear materials. But rather, our concern is with the potential for tort liability claims brought against third parties by nuclear workers at power reactor sites. There are about 75,000 such workers who each year are exposed to small, carefully regulated amounts of ionizing radiation in the course of their employment.

In addition, there are other sectors that may be substantially affected. The annual number of workers exposed to radiation in the medical field exceeds a half million. The number of patients exposed to ionizing radiation for diagnostic and therapeutic purposes was estimated to be 130 million in 1970 and is likely to be much greater today.

We note that section 7 of the Orphan Drug Act does require that there be a rigorous quantitative evaluation of the tables. We think that should be done. We think it remains to be done. We do not believe that a general qualitative discussion of the degree of uncertainty satisfies either the requirements of the act or the needs of those who may use the information or, indeed, the concerns of the President when he signed the Orphan Drug Act.

We believe there is a great danger that the tables will be misused in tort cases and in administrative proceedings, and that the uncertainties underlying the PC values will be forgotten. Judges, juries, referees will tend to assume that the calculations carried out by the scientists to three significant digits are the ultimate truth. We would suggest that at the very least the tables be subjected to a rulemaking type of scrutiny before publication.

We note that the chairman has apparently deferred action on S. 921, which provided a remedy dependent on the tables and now appears to favor an administrative remedy which avoids a great many of the scientific obstacles and judgmental issues inherent in the PC method. Such a remedy, as we understand it, would create a sizable trust fund to pay individual claims and to fund health clinics, health screening, and community programs for the people who live downwind from the Nevada testsite. We believe that such a course is preferable to attempting to assign individual probabilities of causation to each claimant and to develop an individually tailored compensation remedy that could set an unfortunate precedent for our tort and workers' compensation systems.

Thank you very much.

[The prepared statement of Mr. Schmalz follows:]

STATEMENT OF
AMERICAN NUCLEAR INSURERS
MUTUAL ATOMIC ENERGY LIABILITY UNDERWRITERS
NATIONAL ASSOCIATION OF INDEPENDENT INSURERS
ALLIANCE OF AMERICAN INSURERS
AMERICAN INSURANCE ASSOCIATION

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES
UNITED STATES SENATE

SEPTEMBER 18, 1984

I am Richard Schmalz, Counsel to American Nuclear Insurers and Mutual Atomic Energy Liability Underwriters, the two Nuclear Pools that are commonly known as ANI and MAELU. My associates today are Marguerite Shea, Assistant Manager of MAELU, and Joseph Marrone, Vice President and General Counsel of ANI. We have with us Dr. Joseph Fiksel of Arthur D. Little, Inc. Dr. Fiksel is co-author of a comprehensive study of the "probability of causation" concept.

We are also authorized to speak today on behalf of the National Association of Independent Insurers, the Alliance of American Insurers and the American Insurance Association.

The Nuclear Pools, ANI and MAELU, provide both property and liability insurance to nuclear power plants and their suppliers and contractors on behalf of their membership, which includes about 300 domestic property and casualty insurance companies.

The NAII, the Alliance and the AIA are associations of property and casualty

insurers with a combined membership of nearly 850 companies. Workers' compensation and general liability insurance is a significant, important part of their business.

Property and casualty insurers throughout the United States share a deep interest in any proposal that could change substantially the ground rules for awarding damages or compensation benefits under the tort law or workers' compensation systems. Both of these systems today, but especially the tort system, are under great pressure to deliver compensation to more injured persons and in higher amounts than ever before. Under these systems in their present form compensation must be funded solely by private individuals or firms who look mainly to private insurers to spread and control their risk.

The pressure to expand the scope of these privately funded compensation systems raises serious concerns for private industry from several aspects. Expansion which proceeds at too rapid a pace or gets out of control leads to unpredictability and may also result in costs that, in many cases, will be too high to absorb. Aside from the disruption of insurance markets, these developments may adversely affect the financial health of companies in many industries.

That is why the subject of this Hearing takes on more importance than one might think. We have before us a draft of Tables which purport to state "probabilities of causation" for a wide range of radiation related cancers. Preparation of the Tables was directed by Congress in Section 7 of the Orphan Drug Act of 1983.

As Senator Hatch has indicated in a recent public address, the assumptions underlying Section 7 were that there was far more of a consensus among the scientific community than the public realizes, and that reasonable estimates could, therefore, be made of the likelihood that an individual's cancer resulted from a prior specific dose of radiation. It was assumed that the probabilities could be worked out and tabulated.

Again, as the Senator has indicated, the expectation was that if indeed there was a consensus among scientists, Section 7 would ferret it out, and that the revelation could be made in a report that could be understood by reasonably intelligent laymen. The Senator's thought was that if the best estimates of the scientists could be tabulated as the probabilities that link radiation to individual cancers, and the uncertainties in these estimates could be briefly and coherently described, the Tables would be invaluable to plaintiffs, defendants and the courts. They would be useful in determining whether compensation is due under our tort, and perhaps our workers' compensation systems, and if so, how much.

Insurers of course appreciate the value of well conceived and carefully developed probability estimates based on group experience. They are indeed invaluable for many insurance-related purposes, including sound underwriting, the establishment of workable rating classifications that reflect differences in risk and the estimation of expected losses. Thus, insurers can understand the desire to bring more certainty, more predictability into the determination of the casual link between specific exposures to radiation or other carcinogenic agents and individual cancers.

But perhaps because of our own long and extensive experience in working with probability estimates we shared the concern expressed by the President in signing the Orphan Drug Act:

> I am approving this legislation despite the inclusion of a provision about which I have very grave reservations. Section 7 directs the Secretary of Health and Human Services to publish tables showing a causal relationship between radiation exposure and subsequent cancer. The relationship between cancer and low levels of ionizing radiation has long been the subject of research by scientists throughout the world. Despite this intense interest, there is as yet no consensus among radiation experts in relating human cancers and exposure to low levels of radiation. Yet, Section 7 mandates that probability of causation tables be calculated for even very small dose levels.

But we also felt that there was some confusion about what the scientists were saying as to the extent of a consensus about their knowledge of the incidence of cancer among groups of persons exposed to sources of radiation, as contrasted with their ability to pinpoint individual cancers from specific exposures to radiation. These are two vastly different propositions.

An example from insurance practice may help bring this out. Insurance rates for automobile insurance are based on a system of group classifications. Despite the abundance of loss experience that shows that on average the members of the different classes do indeed have different expected accident frequencies, class rates are often criticized as not truly representing the accident frequency of

many, or even most, of the members of the class. It would be ideal, so the criticism goes, if we could only pinpoint the true accident risk of each individual driver. This should not be difficult, as there are millions of automobile accidents every year.

Now this is partly true. There are millions of accidents each year and insurers can collect and analyze this vast body of data. But what is not appreciated is that accidents are still so rare for most individuals that as a practical matter the "true" accident rate of an individual driver cannot be reliably estimated from the driver's own experience. The length of time required for evaluation is too long. For Collision Coverage, even 50 years of experience would still have only a 70% chance of being within 30% of the individual's true accident rate.

Our intuitive uneasiness about the "probability of causation" concept led to a decision by the Nuclear Pools to sponsor a thorough, rigorous study and evaluation. The Pools consulted with actuaries drawn from their members and confirmed that an independent analysis should be made. The Pools accordingly engaged Arthur D. Little, Inc. to undertake the project, and have received a detailed report which we would be pleased to offer the Committee today for inclusion in the record of this Hearing.

We do not want to anticipate Dr. Fiksel's testimony, except to state that it confirms the belief of property and casualty insurers generally that the probability of causation method is not sufficiently reliable, at the present stage of scientific knowledge, to serve as a sound useful procedure for establishing a causal link, under tort or workers' compensation standards, between a specific individual's exposure to radiation and a cancer.

We would like to think that the Arthur D. Little study has contributed to a fuller appreciation within the scientific community of the difficulties of the task which Section 7 poses, especially with respect to calculating probabilities in cases where there are not adequate data and the individual dose of radiation is small or given at a low rate. The Draft Report of the Working Group notes on page iv of the Preface:

> Attempts to estimate the probability that an observed effect resulted from one of several possible causes are not uncommon even in the more exact physical sciences. Decay of short-lived exotic particles in physics, where only a small number of events can be observed and several potential mechanisms exist, is in some respects analogous to the problems involved in constructing radioepidemiological tables. In both cases, probabilities are calculated from a small number of events. There is, however, an important difference. In physics there is a large number of well-tested and comprehensive theories to guide one's calculations, whereas in biology and medicine there are almost no well-established general and predictive theories.

There is also another important difference from a pragmatic viewpoint. When a new scientific theory is applied to physical applications its usefulness can usually soon be tested and evaluated without seriously disrupting practical activity or incurring great financial risk.

But when a new scientific theory or model is applied on a broad scale to a

matter such as awarding compensation to injured persons at the expense of private individuals or firms, there may be a substantial financial impact. Not only is it impossible to verify the model by the results, but it is difficult to mitigate or reverse its effects should the invalidity of the model become clear.

The radioepidemiological tables now being prepared may have just such substantial impact on the insurance that the Pools provide at the 87 nuclear power plants that they insure. The total amount that insurers have at risk is about $9 billion, with a limit of $190 million at each location.

The Pools' concern is not so much with claims from members of the public. We believe the public is well protected from exposure to nuclear material in reactors, but rather our concern is with the potential for tort liability claims brought against third parties by nuclear workers at power reactor sites. There are about 75,000 such workers who each year are exposed to small, carefully regulated amounts of ionizing radiation in the course of their employment.

In addition, there are other sectors that may be substantially affected. The annual number of workers exposed to radiation in the medical field exceeds 500,000. The number of patients exposed to ionizing radiation for diagnostic and therapeutic purposes was estimated to be 130 million in 1970 and is likely to be much greater today.

Section 7 of the Orphan Drug Act directs the Secretary of Health and Human Services to publish an evaluation of the credibility, validity and degree of

certainty associated with the tables. Without a rigorous quantitative evaluation the point estimates made for an individual case will be misunderstood. The fact that they are point estimates which ignore tremendous uncertainties assures this result.

We feel that this quantitative analysis remains to be done and is required by the law. We do not believe that a general qualitative discussion of the degree of uncertainty satisfies either the requirements of the act, or the needs of those who may use the information, or the concerns expressed by the President when he signed the Orphan Drug Act. We believe that there is a great danger that the Tables will be misused in court cases and administrative proceedings, and that the uncertainties underlying the PC values will be forgotten. Judges, juries and referees will tend to assume that the calculations carried out by the scientists to three significant digits are the ultimate truth.

We would suggest that at the very least the Tables be subjected to a rule-making type of scrutiny before publication.

We note that the Senator has deferred action on S.921, which provided a remedy dependent on the Tables, and now appears to favor an administrative remedy which avoids a great many of the scientific obstacles and judgemental issues inherent in the PC method. Such a remedy would create a sizeable Trust fund to pay individual claims and to fund health clinics, health screening and community programs for the people who live downwind from the Nevada Test Site.

We believe that such a course is preferable to that of attempting to assign individual probabilities of causation to each claimant and to develop an individually tailored compensation remedy that could set an unfortunate precedent for our tort and workers' compensation systems.

The CHAIRMAN. Thank you, Mr. Schmalz.

Dr. Fiksel, we are going to put your statement in the record, and we will probably call you later, as these tables come out and are finalized. We do have the benefit of your statement, and we would want to have the benefit of your testimony at that time.

Mr. Gleason, we will now turn to you.

Mr. GLEASON. Thank you, Mr. Chairman. I would ask that my complete statement be put in the record.

The CHAIRMAN. Without objection, so ordered.

STATEMENT OF GEORGE GLEASON, VICE PRESIDENT AND GENERAL COUNSEL, AMERICAN NUCLEAR ENERGY COUNCIL

Mr. GLEASON. Our organization, the American Nuclear Energy Council, which represents a number of companies interested in the commercial nuclear-power field, has taken no position on S. 921, since it is beyond our mandate, dealing as it does with weapons programs and national security matters. Our only interest and the reason we are appearing here today is to call to your attention any impacts, either direct or indirect, which the tables under development or S. 921 might have on the commercial nuclear program.

I will not dwell at any length on our analysis of the validity of the tables. We do share some of the concerns that have been expressed by others. But personally, I am willing to have the tables undergo a peer review and at the conclusion of that peer review, I think the tables will be useful for whatever they are worth. Since we are dealing with a new application of the epidemiological tables, I would urge that we not rush forward with their finalization. Indeed they offer some help in bringing predictability to this important area, I think it would be worthwhile to take whatever time is necessary in order to undergo complete peer review, and I would also endorse the recommendation that Mr. Schmalz made, that perhaps proceeding in the nature of a rulemaking would be useful, in terms of developing a public record, because ultimately the usefulness of the tables will depend on their credibility and we ought to lean over backwards to assure that they have been exposed to the broadest possible peer review. Whatever they are worth at the end of that process, they are worth.

Second, I would like to address some of the procedural issues which were in S. 921, and I am aware that the chairman has now indicated that he would favor an administrative remedy, along the lines of the Marshall Island compact. While we have not analyzed that compact in any great detail, we are inclined to believe that the administrative approach would be preferable. The reason for that is in our concern that in the current state of development of the knowledge in this area, there may not be sufficient validity to the tables or accuracy to the tables to be used, in Mr. Schaffer's words, in a court of law where you are required to determine causation in fact as opposed to administrative proceedings.

The CHAIRMAN. I appreciate that endorsement. When we talk about the compact, the compact would just be a vehicle because we would have to write how the approach would work, and we do have such language. It is a question of whether or not we can generate enough support to be able to add up to the Micronesian compact.

Mr. GLEASON. Whether it is in the nature of an amendment to the compact or a separate piece of legislation, I think the concept of going with an administrative remedy is preferable to the original direction of S. 921, which was an amendment to the tort law.

The CHAIRMAN. But you also agree with me that it would be a little bit untoward to take care of the people in the Pacific Islands without considering the people here in our own country who made sacrifices also.

Mr. GLEASON. I can understand the chairman's desire to compensate the people in this country. As I said, our organization has not taken a position on that matter, because it is beyond our mandate, but I understand why the chairman would feel that way.

We would hope that if you do go the route of an administrative remedy, to the extent that it refers to the tables, it would not require exclusive reliance on the tables and that it would make clear that whatever relevant documentation was available could be used in determining compensation in the administrative scheme.

I would note particularly in that regard, it is my understanding that the Marshall Island compact does contain a provision which explicitly says it is not intended to change existing law. I believe it would be appropriate to include such a provision in your amendment.

So I would just conclude by saying that we are encouraged with the chairman's interest in this most important question and, second, with the flexibility that you have demonstrated in terms of considering all of the approaches to it in order to come out with one which best meets the needs that you are addressing. We think, since your primary focus is on the victims of the fallout from the weapons test program, and that you have not closely examined this issue from the perspective of occupational exposures or whatever exposures due to the commercial nuclear power industry, before you might consider broadening the scope of your inquiry into this, we would have a more comprehensive opportunity to bring to your attention what we think the distinct differences are with respect to the commercial nuclear power program.

[The prepared statement of Mr. Gleason follows:]

STATEMENT BY
GEORGE L. GLEASON
AMERICAN NUCLEAR ENERGY COUNCIL
BEFORE THE
SENATE LABOR AND HUMAN RESOURCES COMMITTEE
SEPTEMBER 18, 1984

My name is Gleorge L. Gleason. I am Executive Vice President and General Counsel of the American Nuclear Energy Council -- a trade association located in Washington, D.C., with a membership of over 100 organizations interested in the commenced nuclear program, including private, public and cooperatively owned utilities, manufacturers, architect-engineers and various firms in the nuclear fuel cycle.

Activities conducted by the Federal Government involving the weapons testing program or other national security activities are not within the mandate of our organization, which is concerned exclusively with the commercial nuclear program. Accordingly, we have taken no position on S. 921 and are not prepared to comment on its provisions. Our exclusive interest and concern is to bring to the Committee's attention any impacts, direct or indirect, which S. 921 may have on the commercial nuclear power program.

The primary focus of this hearing has been on the radioepidemiological tables being developed by the Department of Health and Human Services pursuant to Section 7 of the Orphan Drug Act. Our industry shares a common interest with the Chairman and this Committee in developing a more sound and rational method and methodology for handling claims involving radiation injuries than appears to be developing through case laws. We applaud the Chairman for his efforts in this regard. At the same time, we are concerned, as many others are, as to whether the tables currently under development are sufficient to achieve that objective. Basically, we see merit in many of the criticisms of the tables offered by the nuclear insurance pool representatives and are in agreement with the separate statement, submitted for the record, by the Edison Electric Institute. While, perhaps a step in the right direction, we would recommend that additional opportunity be provided for review and comment on the tables before they are finalized. We also would recommend that further consideration be given to the applicability of epidemiology to the resolution of specific radiation injury claims. If, as a result of these further efforts, we can achieve a better approach to resolving these claims, we will have taken a giant step forward in serving our common interests and the welfare of the public.

I would now like to address the second area of our interest in these hearings, that is, the procedural provisions of S. 921. I have had an opportunity to read the Chairman's remarks delivered on September 6 in Philadelphia entitled, "Medical/Legal Aspects of Radiation Induced Cancer." As I understand it, the Chairman now favors an administrative remedy in lieu of the provisions of S. 921 that would have amended the tort law. The alternative administrative approach is intended to avoid establishing general precedents that might, although not intended, have implications far beyond the atmospheric testing matters addressed in S. 921. While we have not had occasion to analyze in detail the Marshall Island Compact that would be used

as a model for this administrative approach as outlined in the Chairman's talk it appears that an approach along those lines would provide a reasonable and effective way to provide compensation for damages associated with atmospheric fallout should Congress so desire. The emphasis that would be placed on generic remedies, as opposed to individual compensation, would appear to be particularly appropriate in view of the known difficulties in the determination of specific radiation injury claims. I understand that the draft Marshall Island Compact, which has yet to be submitted for Congressional approval, specifically provides that it does not in any way modify existing law. In view of the unique nature of the claims the Chairman seeks to compensate, we would hope that the amendment would contain similar language to assure that it could not be interpreted to establish the general precedents that the approach is designed to avoid. We would also hope that the amendment would provide for consideration of other relevant documentation, in addition to whatever reliance on the Section 7 tables as may be warranted, after the tables are finalized.

We would be pleased to work with the Chairman and his able staff in the further development of this most important matter.

The CHAIRMAN. Let me just ask this panel, do you feel that the courts are coping well with the radiation cancer cases? How might the courts improve their decisions with regard to radiogenic cancer cases? Are the courts coping well?

Mr. SCHMALZ. I think that the courts are having a great deal of problems in dealing with cancer cases where there are very low doses, there is a long latency period, or the type of cases we have been talking about this morning, whether they are chemically induced from pollution or whether——

The CHAIRMAN. So, you agree with Mr. Schaffer that this is a very difficult, problematical problem for courts?

Mr. SCHMALZ. It is.

The CHAIRMAN. It has to be difficult for you, because sooner or later one of these courts is going to come out and lay out some specific guidelines on how you win or lose these cases. If you leave it up to the courts, sooner or later, it seems to me, you face tremendous exposures unless we face these problems.

Mr. SCHMALZ. Well, we face tremendous exposures, no matter what.

The CHAIRMAN. You do, but you may face even worse exposure if something reasonable is not done in this particular area. Yet, at the same time, if something reasonable is done—right now, some people feel that the insurance industry has an advantage. It is so difficult to prove causation, among other things, that the insurance industry is going to win many of the cases brought in open court. On the other hand, sooner or later, you are going to have some adventurous judge decide that this is not right and is going to lay down the groundwork or an American Law Institute rule that says that there is exposure, this is how you prove it, and all of a sudden you are confronted with something that changes the whole Nation's attitude toward these types of tort cases.

I can remember *McPherson* v. *Buick,* what a tremendous ordeal that was to the insurance industry when that case was decided, or any number of other cases that made new law and allowed more exposure and unlimited exposure in tort law at that. I am just

saying, it seems to me, the insurance industry ought to be as interested in coming up with a remedy and a resolution of this problem as anybody. Right now you have an advantage, but that is not going to continue.

Mr. SCHMALZ. You have put your finger on one of the thorniest problems that tort law has had to deal with. I can remember law review articles dating back to the fifties on this problem. I think what we have to do honestly is say to ourselves, at some point of time it may not be possible, despite the best scientific knowledge, to pinpoint individual cancer cases or individual any kind of cases. We ought to be thinking not so much of trying to compensate those victims through the tort system or the workers' compensation system, force them through it, in other words, just to get the job done, but to use some other approach to deal with it. I like the aspects of part of your approach.

The CHAIRMAN. That is what I am suggesting. Maybe we need an administrative remedy that literally allows the probability of risk theory, so that you do not have to meet the more-probable-than-not standard and, in the final analysis, do what is just here. Now, what you may think is just and Senator Kennedy may think is just may be somewhat different. My worry is that either might be able to set the tone of the total problem here, either the insurance industry or the more liberal point of view in our society.

Mr. SCHMALZ. There is one aspect of your suggestion, as I see it. It is relatively easy—and I think all the scientists agree; do not think there is any dispute among Arthur D. Little, and I do not think there is any dispute among those scientists who testified today. It is relatively a much easier task to assign an increased incidence of cancers to a group, without trying to identify the individual. If you can base some kind of a remedy around that concept, that you compute the increased incidence for a group of industries, we will say——

The CHAIRMAN. Then provide a means for the individuals of the group to somehow get their share of that?

Mr. SCHMALZ. And allocate a proper fair share of compensation, using the tort standard as a workmen's compensation standard on an average basis or whatever, so you keep the whole set books in balance, and then use an administrative remedy——

The CHAIRMAN. You seem to be making a very good case for what I would like to do.

Mr. SCHMALZ. I am saying, I find a lot of sympathy for the idea that you have, to stay away from trying to do it on an individual case.

The CHAIRMAN. What you are afraid of, if this goes to open tort law, you are going to have different results because of different attorneys, different juries, different judges. There is unlimited exposure, and yet certain people who should compensate sometimes lose because they do not make good enough witnesses to win the amount of compensation they really deserved. There are a lot of inequities in an open-ended tort system.

Mr. SCHMALZ. There are.

The CHAIRMAN. So if I understand you correct, you are saying, "Senator, more power to you, if you can set up a trust fund to compensate those victims of atmospheric testing that would provide for

a probability of risk theory and give them a shot at having some compensation before they die or their families die and do what is just in this matter?"

Mr. SCHMALZ. Do what is just on a group basis. I think that we would have no problem with that.

Mr. GLEASON. May I comment on that?

The CHAIRMAN. Yes.

Mr. GLEASON. I read into your summary statement there something more than I think I would have stated had I been stating it myself. We do endorse the general approach of an administrative remedy for the unique situation which you are trying to address, which is the fallout victims.

The CHAIRMAN. I am limiting it to the fallout victims. I am not going beyond that.

Mr. GLEASON. When you have a situation where the records are incomplete, if available at all, and you really do not have any good roadmap to determine compensation on a rational basis, your approach makes a great deal of sense. However, looking at the broader picture of how these tables might ultimately be used in other applications, there are substantial differences.

In the nuclear industry, for example, I think the scientists pointed out the voluminous data which we have available there. That is a different type of circumstance. Even if ultimately you were to set up an administrative approach for those types of cases, I think you would want to bring to the causation determination more certitude than you would require in a situation like the fallout victims. So we would want to look much more critically in that context at the bands of error which may be incorporated into the epidemiological tables.

When you clear away all of the verbiage, we all understand that epidemiology distinguishes classes not individuals. That is your burden in tort law. Our endorsement of your approach here, which is unqualified to the extent that it deals with the fallout victims, we would characterize our approach to the broader problem in a much different fashion. So I do not want you to believe that we are endorsing the administrative approach after all.

The CHAIRMAN. No, no; I did not take that for a second from Mr. Schmalz either. I just want to say this, both of you have been very honest with this committee, and I very much appreciate it. I am concerned about the overall problem. I think something has to be done. I think it has to be done intelligently, and I think it has to be done in a just and reasonable and good way. But I am really concerned when we have had to fight now for almost 8 years to get the Government to admit that it was negligent with regard to the fallout victims. Finally, they are admitting that they are negligent, and the court case found that they were negligent, and they have only admitted it since then. I think we have proved an overwhelming case of negligence.

There is also, in my opinion, an overwhelming case of people suffering as a result of the atmospheric tests, the failure to warn and a whole variety of other negligent and failure-to-warn situations with regard to the downwind people in our three States out there. Now, I believe that we should work together to resolve the whole problem for the whole industry. I believe that the nuclear industry

will never have as much chance to succeed as it will when we have a just and equitable and reasonable system of compensating victims of nuclear radiation wherever they arise. But I am interested in solving this one problem, and I want to get that solved, and I want to do justice, which has not been done up to now and which people are starting to believe needs to be done.

I particularly appreciate the testimony both of you have brought here today. You have both indicated that in this may be the way to solve this problem.

Mr. Marrone, you are anxious to say something?

Mr. MARRONE. Yes. I wanted to say, Senator, that our testimony was sort of an introduction to the Arthur D. Little Co. report.

The CHAIRMAN. I will put that in the record, without question. I intend to and probably will call Mr. Fiksel at a later date.

Mr. FIKSEL. Senator, I wonder if I might make a short comment.

The CHAIRMAN. Sure.

Mr. FIKSEL. Having taken the time to come all the way here.

The CHAIRMAN. Of course, we did not invite you. If I had invited you, it would have been another thing. Now that you are here, make a short statement. I am pressured for time. We will put your statement in the record, and I will give you an opportunity in the future to comment.

Our purpose today was to go over their preliminary draft, and this is a preliminary hearing. When they get the final draft, we are going to have the other side come in as well and say what is right or wrong with this thing.

Mr. FIKSEL. I appreciate your indulgence, and I do not plan to read my testimony; that has been submitted. But I would like to offer a cautionary word, in terms of the use of risk theory in compensation. I am an expert in risk theory, and I believe that there has been some misinterpretation of the underlying theory. I believe that the issue of causation is not well understood here, and I would submit——

The CHAIRMAN. Oh, I think we understand it very well. The question of whether we should use a probability of causation theory is still up in the air.

Mr. FIKSEL. Senator, I submit that the probabilities of causation that were developed by the committee are not truly probabilities. In fact, the Oversight Committee of the National Academy of Sciences has so stated in their review.

The CHAIRMAN. We will see what they say when they testify.

Mr. FIKSEL. In fact, I can quote you from the report of the National Academy: "The expression 'probability of causation' has several misleading features. The quantities calculated are not probabilities but proportional shares."

The CHAIRMAN. Mr. Fiksel, you are talking semantics now——

Mr. FIKSEL. Not at all.

The CHAIRMAN. You are talking semantics, and you are talking legal theory. I do not think that the preliminary report, the draft report that we have right now, is going to answer all of the legal theories or legal problems that we have. We are going to make that determination as Members of Congress. What we hope the draft report, and finally the final report, will do is give us some basis, statistical or otherwise, upon which to base a resolution of these

problems. I am going to be very interested in reading your report, and I am going to be very interested in hearing from you at a later date. But let me suffice it to say for today's hearing, I wanted to get this matter out, I wanted to ask questions about it, and I wanted to have the public realize that these tables are on their way to being done and to have some idea about what is being done.

We will put yours in the record and everybody who is interested can read what you have to say. We will give you another opportunity to speak to the committee.

Mr. SCHMALZ. Senator, may I ask your indulgence?

The CHAIRMAN. Yes, Mr. Schmalz.

Mr. SCHMALZ. There were some direct references made this morning that indicate that the Arthur D. Little report was misunderstood.

The CHAIRMAN. It was treated fairly harshly in the testimony earlier, I have to admit.

Mr. SCHMALZ. I wonder if it would be fair if Dr. Fiksel could just send a brief statement to respond specifically to those things, before the points are forgotten?

The CHAIRMAN. Sure. I will allow that.

Mr. FIKSEL. I did make a note of the criticisms that were raised. I was surprised to hear those criticisms because in fact we met several times with the members of that committee, and they were afforded several opportunities to review our work and apparently agreed with the report in its final version.

The CHAIRMAN. Wait. We do not have Dr. Rall here. Mr. Jablon, is that a correct statement, the one he just made?

Mr. JABLON. The working group did not meet with the Arthur D. Little representatives. There were some meetings, as I recall, with some members of the NCRP committee meeting with representatives of Arthur D. Little. As I recall, we had some disagreements at that time.

Mr. FIKSEL. We also had substantially more agreement, Senator, in all fairness, than was characterized by the earlier remarks.

The CHAIRMAN. It is good that we have this opportunity to bat this around.

Mr. FIKSEL. I want to be very brief, and I do not want to talk in technical jargon, Senator. Let me make something clear. The use of risk analysis in order to compensate individuals involves tremendous uncertainties. The estimation of the risk associated with a particular individual could vary by at least a factor of 10. The result is that the numbers that emerge from the formula, in spite of the use of the best available evidence, may not be good enough. It may not be accurate enough.

The criticisms that were raised in our report were, first of all, that we dealt with mutual exclusivity, and that was something that Mr. Jablon could not understand. If I may, I want to quote you very briefly from my testimony on that particular point: "The probability of causation formula presupposes that one and only one factor is the cause of a cancer. Otherwise, the PC for a single factor is meaningless."

The CHAIRMAN. I did not take their testimony that way, though. I do not think they testified that way here today.

Mr. FIKSEL. The probability of causation formula implicitly assumes that one factor is responsible. Otherwise, you cannot talk about the probability of causation for radiation alone. The fact is that radiation interacts with other factors in causing cancers. When Mr. Jablon speaks of the "excess risk" imposed by radiation upon a population, he is implying that radiation, in combination with other factors in that population, produces certain cancers. Therefore, no individual cancer can be attributed to radiation alone. We can never prove or demonstrate that radiation was the sole or single cause. That is why we have to deal with joint causes. Unfortunately, the PC formula does not provide any mechanism for attributing responsibility among joint causes, and in fact that is not scientifically possible, because we do not know what the mechanism of cancer is. That is still a scientific frontier.

My fear is that this approach will potentially mislead people into thinking that science has solved this basic issue of the mechanism of carcinogenesis, and that we understand the relative contributions of different factors. We do not.

The CHAIRMAN. Let me say this. I did not interpret their testimony the way you did. I think that they were talking about a proportional basis, and frankly I do not think they differed with what you said, as far as there is no one way of proving which cancer came from what. I thought they made themselves pretty clear.

Mr. FIKSEL. Yes; there is no way of proving that.

The CHAIRMAN. But they did, on a statistical analysis and other bases, determine what they consider to be the probabilities of risk that this particular cancer was caused by radiation.

Mr. FIKSEL. The formula claims to calculate the likelihood that radiation caused a cancer. Now, that implicitly assumes that there was a single cause. That is my point.

The CHAIRMAN. I did not interpret it that way.

Mr. FIKSEL. It has to be interpreted that way, because if not, you are going back to the Dr. Gofman interpretation, who says that the formula calculates the share of a cancer. In fact, that interpretation in a certain sense is more correct, because every cancer must be considered as a combination of all the factors that have acted on that individual in some unknown manner and not as a result of any one of those factors in isolation.

The other criticism of our report that was raised was that we dealt with a slightly different formulation of the PC formula, and that is true. The earlier version of the PC formula, which Dr. Bond first put forth, was slightly different in its mathematical form. However, the basic criticisms remain. The so-called conditional approach that has been adopted by the committee assumes a relative-risk model. In a relative-risk model, the excess risk due to radiation does not depend on the presence of other factors. That is quite correct. The problem with that is, the relative-risk model is an arbitrary choice of a model. It is supported by some of the data, and it is not supported by some of the data. There is a competing model which is called the additive model, which has equal support. I think you will find scientists on both sides. Essentially, the story is not yet complete on which model is appropriate for which effect.

The relative-risk model, therefore, is an assumption and assumes that the interaction of radiation with other materials is essentially

independent of the presence of those materials, that it is a simple multiplicative relationship.

The CHAIRMAN. OK.

Mr. FIKSEL. I would like to also stress something, that the use of this formula in the context of compensation for radiation, may lead others to seek to apply this formula in the context of toxic wastes——

The CHAIRMAN. Well, that is for another day. We understand that there are those who would try to expand upon what we are trying to do.

Mr. FIKSEL. I have a great fear that risk analysis will be misused.

The CHAIRMAN. We understand that, and we understand the insurance industry's fear of that. Anybody with brains has to understand that. We cannot solve all of these toxic tort and toxic chemical problems with what we are trying to do here in the field of radiation. But I will say this to the industry: until the industry realizes that it has liabilities and obligations, as well as opportunities—and I do believe many in the industry do realize that—there are always going to be those who make arguments that there should be no consideration of nuclear power in the economic and other realities that exist in modern America. I do believe we have to solve these problems. What I am limiting my solution right now to happens to be a very serious set of problems in the three States resulting from the atmospheric tests. If there is enough support to try and resolve this on an industry-wide basis, including all problems arising out of radiation exposure, I am willing to try and do that because I think it would be in the best interest of everybody to resolve that problem.

I come from a legal background where I have tried both sides. I have defended cases and I have brought them. So I understand the viewpoints of both sides. I have represented insurance companies in defense of insurance claims, and I have represented the other side against insurance companies. So I understand how you feel. I understand what the problems are. As chairman of this committee, I am not interested in supporting any one group except my people in Utah, and Arizona, and Nevada because they are part of our people; they are our neighbors. I am interested in solving that problem.

With regard to the whole industry, if we solve that problem, it is going to be in a fair and equitable, decent, workable basis. I assure you, that is all I am interested in there. But I have been surprised that more in the nuclear industry have not come forth until recently to support us in our desire to solve this atmospheric testing problem. It is clearly an injustice, and something needs to be done. I agree, there is no simple, clearcut, statistical or other way of proving who did or did not get cancer as a result of even the fallout. I think we can make an overwhelming case in some cases out there, but not in all of the claim cases.

We need to have some reasonable way, some equitable system, some just approach that will right these wrongs that have occurred to my people and our neighbors out there in that area. That is why I have appreciated you, Mr. Schmalz, here today and you, Mr. Gleason, and your testimony saying you agree with that, that there should be some reasonable way of solving these problems. You are

not quite sure how, but you think this may be a reasonable way. I think that is important, to have people from your end of the industry who really are concerned about exposure come in and lend support to this, at least to the limited degree that you have here today.

I understand that, but I am suggesting to you, there is a lot more to this issue. As somebody who believes that we should develop all forms of energy for the benefit of our country, there has to be responsibility with that development of energy. I suggest to you that we have to come up with responsible ways of resolving these problems across the board. But for right now, I am interested in one thing, and that is doing justice to my people out there in Utah and our neighbors. If I can get that done, that will be a long step in the right direction.

Now, if we go with the probability of risk theory, to do that one, we know that all over the world people are looking at that today as a possible resolution of what really are monumental problems. We may learn a lot from this. I think people have learned a lot, and I have seen a lot of people who were totally opposed to what we have been trying to do coming around, saying the Senator is not trying to stick it to the nuclear industry, nor is he trying to boost the nuclear industry; he is trying to do what is right. I think you are better off with someone like me trying to do what is right than you are with some people who have their own axs to grind. I do have an ax to grind with regard to my folks in Utah and our neighbors in the other States. I really have an ax to grind, and I am not going to quit until we grind that ax. Now, I might not win, but by gosh, they are at least going to know they have been in a battle. I think people do know that.

I hope we can resolve this, because it would be fair, just, equitable, and right to do so. Now, I did not mean to cut you off in your testimony, because I think it is important, and I think you ought to have the right to explain your report. We will put your report in the record, but I would also like to keep the record open for a written response to anything that anybody has said that you differ with as far as your report is concerned. We will do that, in all fairness to you.

This hearing has not been to have a debate. This hearing is to get out the report and let people start understanding it, looking at it, and let us see where we go from there. And, I might add, not only understanding and looking at it but criticizing it. Sometimes science can benefit from criticism as well as anybody else. If the criticisms are just, I have a deep feeling that these people who have helped to formulate this report will accept the just criticisms and change the report. And keep in mind, this report which will come forth is only the first of a long series of them, as far as I am concerned, because I want these updated every so often, periodically, and I do believe we ought to have a line item in the appropriations process to resolve this and keep it updated so that we can be as just and as accurate as we possibly can. You, as a statistician, I am sure, would agree with that.

[The prepared statement and report of Mr. Fiksel follows:]

STATEMENT OF

JOSEPH FIKSEL, PH.D.

ARTHUR D. LITTLE, INC.

BEFORE THE COMMITTEE ON LABOR

AND HUMAN RESOURCES

UNITED STATES SENATE

SEPTEMBER 18, 1984

I am Joseph Fiksel, Manager of the Decision and Risk Management Unit at Arthur D. Little, Inc., the international research and consulting firm. I am testifying at the request of American Nuclear Insurers and Mutual Atomic Energy Liability Underwriters, who recently sponsored an Arthur D. Little, Inc. study of the "probability of causation" method.

Arthur D. Little, Inc. provides objective, state-of-the-art consulting services to both government agencies and private industry regarding the methodology and practice of risk assessment. I have directed a number of major studies for agencies such as EPA, NASA, and NSF to investigate the potential hazardous effects of materials

released into the environment, focusing on mathematical methods for quantifying and predicting these effects.

In particular, I have specialized in the development and application of risk assessment models for estimating the chronic risks to humans associated with exposure to chemicals and radiation. Since my formal training is in applied mathematics, I have collaborated closely with physicists, biochemists, toxicologists, and epidemiologists in the performance of these assignments. My work has been published in numerous professional journals and presented at scientific conferences both in the United States and abroad.

INTRODUCTION

The issue of compensation for cancer claims has received increasing attention from Congress, regulatory agencies, and the courts, due to public awareness of the potential latent health effects of exposures to toxic substances and ionizing radiation. Compensation systems ordinarily require proof of a causal link to provide compensation for those who may have been harmed by such exposures. However, there is often difficulty in defining and establishing causation. When an individual has been exposed to several causal factors and subsequently develops cancer, medical science cannot definitively say to what extent each factor may have contributed to the cancer.

To overcome this difficulty, some scientists have suggested the use of a "probability of causation" (PC) measure, which would estimate the likelihood that a particular claimant's cancer was in fact attributable to radiation exposure (or to any other factor). Essentially, the PC method takes the ratio of the excess risk imposed by radiation to the total risk of cancer in the exposed population. This PC approach has been proposed as a basis for determining a claimant's eligibility for compensation.

To illustrate, suppose that the normal annual incidence rate for leukemia in males aged 30 to 34 is 28 per million, and that the excess risk due to two additional rads of exposure is 4 per million

(i.e., the total annual incidence of leukemia in exposed males is 32 per million). Then, according to the proposed approach, if a leukemia victim is selected at random from the exposed population, the "probability" that radiation caused his leukemia is 4/32 or 12.5%. Some have suggested that this sort of ratio could be used to determine eligibility for compensation by testing whether a claimant's PC exceeds a judgmentally-established threshold value.

It has also been suggested that calculated PC values could be used in allocating compensation among those eligible. For example, if 100 cancer claimants are identified, each with a PC of 10%, the assumption is that about ten of them have a cancer that was caused by radiation, and the remaining ninety by other causes, including normal cancer incidence. Since these ten could not be identified, one policy approach might be to distribute compensation for the unidentifiable ten victims among the entire group of 100. Moreover, it has been suggested that if claimants have different PC values, they might be assigned compensation in proportion to their respective PC's.

This type of compensation proposal, although superficially appealing, raises some important technical questions regarding the capabilities and limitations of current science, quite apart from legal questions or questions of fairness. The recent study by Arthur D. Little, Inc., which has been submitted for the record, has revealed some

serious deficiencies in the PC approach. Specifically, it was found that the proposed PC formula does not yield a true probability of causation. It implicitly assumes a "competing risks" model, which conflicts with current scientific understanding of the mechanism of carcinogenesis.

In fact, it appears that calculation of probability of causation in the presence of joint causes is not possible, and that any proposed formula for assigning shares of causation necessarily requires trans-scientific policy choices. However, the PC approach does not articulate or support policy judgments regarding allocation of responsibility among joint causes. Furthermore, if the present approach were adopted for administrative convenience, significant uncertainties in the required data would make it an unreliable and potentially biased instrument.

The Orphan Drug Act of 1983 requires the Department of Health and Human Services to prepare "radioepidemiological tables" giving probability of causation estimates for a range of radiation dose levels. Unfortunately, it is now clear that PC cannot be objectively defined in this context. Nevertheless an ad hoc Working Group established within the National Institutes of Health (NIH) has developed formulae and tables to be used as a basis for PC calculations. Their work has been reviewed by an Oversight Committee formed by the National Research Council. Both the Working Group and

the Oversight Committee have acknowledged deficiencies in the PC method, but have been obliged by their mandates to complete their respective tasks. At this point in time, it is important that the inherent limitations and assumptions of the PC method be clearly understood, and that the very substantial margin of error be quantified.

I will now briefly summarize the key conceptual issues that limit the usefulness of the PC method, and I will then touch upon some pragmatic concerns about implementation of the method.

CONCEPTUAL ISSUES

Indeterminate Causation

The most important conceptual limitation of the PC formula is its implicit assumption that causes of cancer are mutually exclusive. This point has been considerably debated, and is of fundamental importance. The formula presupposes that one and only one factor is the cause of a cancer; otherwise the PC for a single factor is meaningless. However, in reality several factors are likely to be jointly responsible for a cancer. For example, factors may be co-carcinogenic, or some may act as initiators and others as

promoters of a tumor. In such cases, it is not meaningful to speak of a single factor, e.g., radiation, as "the" cause. Instead one must ask whether a particular combination of factors could have caused the tumor. However, we cannot answer this question with our present scientific knowledge.

It is interesting to note that, in a recent worker's compensation case in California, an expert witness argued that whenever radiation is present it must always be implicated as a contributing cause. Ironically, the expert suggested a formula similar to the PC formula for attributing a share of responsibility to each factor. However, neither interpretation of the formula has been justified. It has been shown that to properly attribute shares of causation, it is necessary to consider incremental risk contributions from different factors over the entire range of exposures.

In summary, to overcome the problem of indeterminate causation in the presence of multiple factors, the PC method makes an unrealistic "all or none" assumption about the mechanism of carcinogenesis. It asserts that each cancer was or was not caused by radiation, and thus fails to allow for the possibility of partial causation. Only by assuming exclusivity of causes can one correctly speak of "probability of causation".

Choice of Partition

A further difficulty in the use of PC concepts for compensating individuals is the problem of partitioning the populations from which comparative epidemiological data are drawn. The PC method requires information about cancer incidence within broad classes of people such as male smokers, and may be applied to compensation of specific individuals only by assuming that each individual is an "average" person drawn from one of these classes. Therefore, the PC that is computed for an individual will be different depending upon the class to which he or she is assigned. Thus, the same claimant might have a different PC depending on whether he was considered an average 34-year-old male, an average 34-year-male smoker, or an average 34-year-old smoker with a family history of cancer.

Unfortunately, for practical reasons, it is not possible to develop procedures or tables that reflect all relevant population characteristics which might influence cancer incidence, such as diet, lifestyle and genetic factors. To do so would require partitioning the population into an unmanageably large number of classes, with little or no data available to describe each class. The solution adopted by the NIH Working Group was to partition the population by sex, age, and tobacco use; as a result, the variability of individual characteristics within a class is extremely wide. The only way to account for such variations would be to adjust the PC values for

every individual, which would require laborious and often speculative calculations.

The practical implication of this partitioning problem is that the PC calculated for an individual based on class characteristics are likely to give little or no information about the "true" value of that person's PC ratio.

Choice of Risk Models

The development of cancer risk estimates for low levels of radiation requires the use of dose-response extrapolation models, which infer the probable response rate at low doses based on data for human populations exposed to much higher doses, such as the Japanese A-bomb survivors. A great deal of effort has been expended on this extrapolation problem by the National Academy of Sciences BEIR Committee, which admits that its best estimates are still fraught with uncertainty. The linear-quadratic model used by BEIR cannot be validated empirically, and it might overstate the true risks at low doses. Yet the BEIR data represent the best information currently available, and have been incorporated into the calculation procedures recommended by the Working Group. While a theoretical model may be acceptable for regulatory purposes, its use in compensation decisions must be questioned.

In projecting the risks associated with radiation exposures to different population groups, one of two alternative methods is generally chosen. The absolute-risk approach assumes that the excess risk due to radiation is constant, regardless of the baseline incidence in the unexposed population. This leads to an "additive" interaction model when more than one factor is present. The relative-risk approach assumes that the excess risk due to radiation is proportional to the baseline incidence in the unexposed population. This leads to a "multiplicative" interaction model when more than one factor is present. These two approaches may result in significantly different predictions, particularly when baseline incidence is influenced by other carcinogenic factors. Since there are not adequate data available for selecting between them, the Working Group has been forced to make arbitrary choices in several instances. In fact, their use of an absolute-risk model for interpreting the Japanese data appears inconsistent with their use of a relative-risk model for computing PC.

These difficulties in the choice of risk models contribute to the uncertainty inherent in the PC calculations, and are unlikely to be resolved in the near future.

Interactions among Factors

A final significant difficulty with the PC method, related to the problems of mutual exclusivity, partitioning, and risk estimation

described above, is the presence of interactions among various carcinogenic factors.

As noted by the Working Group, there are many exposure factors that are believed to contribute to cancer incidence, including exogenous factors such as smoking, alcohol consumption, dietary intake, occupational exposures, environmental pollution, medical procedures, sexual behavior, and viral infections, as well as host factors such as race, ethnic group, and genetic predisposition. There is increasing recognition that the majority of human cancers result from a complex interaction between these host and environmental factors, involving a multi-stage biological process.

The NIH Working Group has sought to provide formulae for quantifying interactive effects, but there is a severe lack of scientific knowledge concerning the mechanisms and magnitudes of interaction between radiation and most other factors. Moreover, as mentioned earlier, the multi-factor etiology of cancer raises difficulties in attribution of cause to any one factor. The assignment of shares of responsibility implied by the PC formula is an arbitrary choice of a risk accounting mechanism, and other equally plausible formulae can easily be constructed.

In fact, the use of any mathematical formula for compensation decisions will reflect a policy choice, and cannot be viewed as an

objective or scientifically valid procedure. Assignment of responsibility among joint causes must ultimately involve trans-scientific value judgments, and cannot be based on statistical arguments alone. For example, criteria of intent, knowledge, and foreseeability might be included in assigning compensation, so that voluntary and informed exposure to medical radiation would be regarded differently than involuntary exposures.

PRAGMATIC ISSUES

In spite of the above-mentioned difficulties, it has been argued that the PC formula is the best that contemporary science has to offer. Though it does not represent a true probability and is subject to large uncertainties, it might nevertheless be viewed as a satisfactory policy tool for assigning compensation in the absence of adequate information. In other words, might PC be "good enough" for practical purposes? Before reaching such a conclusion, it is important to assess both the reliability and credibility of the PC method in terms of certain pragmatic criteria. A model which is at best a crude approximation of reality may be appropriate for some applications, but may be inadequate or even disruptive in certain contexts.

Risk Attribution Bias

An important pragmatic concern about the PC approach is the bias introduced by focusing on a particular radiation exposure as a cause of cancer. The sources of radiation exposure are numerous; background and medical radiation alone are estimated to give the American public an average annual dose which is 350 times as great as the average exposure to the public and to workers from the nuclear industry. In addition, there are hundreds of naturally-occurring and man-made chemicals which are suspected carcinogens, yet quantitative risk data are available for only a few of them.

Notwithstanding the profusion of carcinogens, it is widely acknowledged that the majority of human cancers cannot be attributed to environmental or occupational exposures. According to recent estimates, over 80% of cancers are due to diet and lifestyle factors, although the interactions among various factors remain poorly understood. As a practical matter, only the identifiable and quantifiable causes of cancer can be included in the PC formula; this will tend to penalize those causes that have been extensively studied. Specifically, there may be a tendency to overestimate the importance of ionizing radiation relative to other causes.

Sources of Uncertainty

The most important pragmatic limitation in the PC approach is the presence of many uncertainties that enter into the prescribed formulae. If the variability of the data utilized as inputs to the formulae is sufficiently great, then little credibility can be attached to the resulting PC values. A number of significant sources of uncertainty are discussed in the ADL report, the draft report of the Working Group, and the interim report of the Oversight Committee. These include retrospective dose estimation for exposed individuals, ethnic and regional differences in cancer incidence, temporal factors such as dose rate and latency period, effects of excluded risk factors, and extrapolation from high to low doses. However, the Working Group did not attempt the difficult task of quantifying these uncertainties.

While the net impact of all of these uncertainties is difficult to estimate numerically, it is plausible that the cancer risk estimated for a particular individual could vary by a factor of ten or more. Since risk analysis is an inexact science, this is not unusual, but uncertainties of this magnitude may be unacceptable in the context of compensation decisions. The effect of these uncertainties is magnified when a ratio of risk rates is computed, as in the PC formula. It can be shown that even if one overlooks the fundamental conceptual flaws in the PC approach and assumes that the model is

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valid, then the confidence bands around calculated PC values tend to be very wide. For example, if the calculated PC for radiation for a particular cancer claimant is 51%, the "true" value under perfect information could plausibly range from about 9% to about 92%.

If PC values are used to determine eligibility for compensation, the chances of incorrectly granting or refusing eligibility are large for PC values near the threshold cutoff level. To illustrate, if 100 people are selected from a population of claimants as being eligible for compensation, based on their having a PC value slightly exceeding a threshold of 10%, then about 50 of them will be incorrectly chosen; that is their "true" PC will be below 10%. Of course, even among those that are correctly chosen, only about 5 will have cancers "caused" by the factor in question (e.g., radiation), according to the PC model. Again, this calculation assumes the validity of the PC formula; if one acknowledges the conceptual deficiencies mentioned earlier, the question of accuracy becomes moot.

CONCLUSION

The NIH Working Group has made a valuable contribution to our understanding of radiogenic cancer risks. Nevertheless, the proposed PC approach suffers from a number of serious shortcomings that make it questionable as a basis for compensation. These include fundamental conceptual problems -- the problem of joint causation,

the choice of a population partition, the choice of risk models, and interactions among risk factors — that make it impossible to calculate a meaningful probability of causation.

On the practical side, the use of a formula for assigning shares of causation will be hampered by biases in risk attribution and by large uncertainties in the input data, which render the output of the formula unreliable and perhaps even arbitrary. It appears likely that any effort to compensate claimants through the use of a computational model will involve an unsatisfactory compromise between biological realism and mathematical simplicity.

Finally, the PC approach fails to address the trans-scientific social and ethical issues which should have a bearing on compensation decisions. The choice of a compensation mechanism is a policy question that cannot legitimately be solved by statistical methods or objective formulae based on scientific knowledge alone.

Report to
American Nuclear Insurers
and Mutual Atomic Energy
Liability Underwriters
March 1984

A Critical Review of the Probability of Causation Method

by
Louis A. Cox, Jr. and Joseph R. Fiksel

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Arthur D. Little, Inc. *Reference 50041*

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1. INTRODUCTION

There has recently been considerable debate over how to compensate cancer victims who have been exposed to multiple carcinogenic factors, including ionizing radiation. For example, if a worker who smokes cigarettes is exposed to radiation in an occupational setting and subsequently develops lung cancer, the exact cause of the cancer cannot be determined. Radiation exposure may have been wholly, partially, or not at all responsible for the cancer, but medical science cannot definitively say which occurred. Several Congressional bills have proposed methods of compensation for toxic substance or radiation injuries, and questions of liability in cases of multiple causation have frequently arisen in the courts. A number of government and private groups are studying these issues, including the National Institutes of Health, National Academy of Sciences, National Council on Radiation Protection, and Chemical Manufacturers' Association.

While much of the current debate centers upon the actual magnitude of the risks to the public, and on the adequacy of existing legal remedies, this paper examines certain fundamental scientific questions that are frequently overlooked. To what extent can an individual's exposure to radiation or to a toxic substance be linked to the subsequent occurrence of an effect such as cancer? Does current science permit us to estimate the likelihood that a specific factor, such as prior exposure to radiation, gave rise to an observed effect in an individual? If such estimates are possible, what are the associated levels of uncertainty?

Inasmuch as present legal and administrative mechanisms seek to compensate individuals for injuries, the above questions must be addressed. For example, the tort system seeks to compensate injured individuals, but only for injuries that are caused by the "wrongful" conduct of others. Carcinogenic effects of low-level exposure to toxic materials or radiation often have long latency periods, and generally cannot be distinguished from the effects of other factors, such as

dietary habits or tobacco usage. The difficulty of establishing direct cause-effect linkages in such cases poses a substantial challenge to any system of reparations that requires the probable cause or causes of a cancer to be determined.

In searching for an objective means of allocating compensation for radiation-induced cancers, some have proposed the use of a "probability of causation" measure [1]. The probability of causation (PC) has been defined in this context as the ratio of the cancer risk attributable to a particular radiation exposure to the total cancer risk due to all causes. Essentially the PC attempts to measure the likelihood that an individual's cancer risk can be attributed to a particular cause. It has been suggested that if the PC could be accurately estimated for each claimant, it could be used as a basis for accepting claims that exceed a minimum probability level, or for setting compensation amounts. This approach has already been considered by the Hatch Committee in the context of the Orphan Drug Act, enacted on January 4, 1983 [2]. The Department of Health and Human Services is required by this Act to prepare radio-epidemiological tables that permit PC estimation, and a preliminary version of these tables has already been developed. It is not clear at this time exactly how these tables will be used.

In view of the recent surge of interest in using PC calculations for compensating radiation injury claims, it is important to examine critically the scientific foundations of probability of causation. Congress could be setting a major precedent if it endorses the PC approach as a basis for compensation. Some investigators already have examined the potential implications of PC-based compensation schemes for workers in the nuclear industry [3]. The method could conceivably be adopted in future legislation related to occupational illnesses, hazardous waste exposures, and other environmental concerns unrelated to ionizing radiation. Generally speaking, the economic and legal impacts

upon the public, the courts, and the industries involved could be far-reaching. Therefore, while the use of a mathematical formula for compensation may be appealing from an administrative point of view, it is important to ascertain both the adequacy of the scientific information available to support its use, and the soundness of the concepts behind the formula.

The purpose of this report is to inquire into the theoretical basis and pragmatic feasibility of the PC approach. There appear to be a number of obstacles to the development of defensible and credible PC estimates, and these are identified and discussed. Although the emphasis here is on PC as applied to radiation injuries, the findings are relevant to other types of carcinogenic exposures where the PC formula might be applied. The great uncertainties associated with risk estimation for chemical carcinogens make the application of the PC method for toxic substances considerably more problematic than for radiation.

In general, pioneers of the PC methodology have been careful and responsible in documenting many of its important limitations. Nothing in our report is intended as a criticism of their efforts. Rather, our principal concern is to make potential users of the probability of causation model aware of its present deficiencies, to help forestall an overly hasty acceptance of a developing methodology that may not yet be suitable for practical application, and to encourage further research in this important field.

The paper is structured as follows. Section 2 describes the underlying principles of the PC approach and some of its general limitations. Section 3 then examines the difficulties in attributing an effect to one of several causative agents, and discusses conditions that must be met in order for the PC approach to be useful. Section 4 addresses the many sources of uncertainty that arise in estimation of the cancer risk due to a particular causative agent. Finally, Section 5 summarizes the findings and conclusions. Additional technical arguments and examples are presented in the Appendices.

2. UNDERLYING PRINCIPLES OF THE PROBABILITY OF CAUSATION METHOD

2.1 The Problem of Risk Attribution

The science of epidemiology characterizes disease patterns in groups of humans and seeks to identify the factors that influence these patterns. Most of the previous work in risk analysis of health effects has been oriented toward developing statistically-based predictions of the future incidence of disease in human populations, based on observed historical incidence rates. This is essentially a use of information regarding past effects to obtain prospective risk estimates for classes of individuals, and stands in sharp contrast to the retrospective analysis of causal factors associated with an individual's observed health effect, as in the PC approach.

The concept of attributable risk has been used frequently to describe the increase in health risk due to a specific causative agent. The a priori cancer risk attributable to a given level of radiation is usually defined as the expected increase in incidence of cancer in a population exposed to that level of radiation, compared to a matched population that is not exposed. Estimates of attributable risk may be obtained statistically by comparing exposed to unexposed populations. As will be seen, attributable risk plays an essential role in the PC method.

The question of risk attribution a posteriori must be handled differently from conventional epidemiological predictions. If a specific individual is observed to have cancer, then the question arises: was his cancer caused by exposure to a specific source of radiation? This question cannot be answered with certainty, but an attempt can be made to compute retrospectively a "probability of causation", which estimates the likelihood that the cancer was caused by a particular radiation exposure and not by some other causative agent, such as medical or background radiation, or exposure to chemical carcinogens. However, the only information about human risk incidence available to support the PC

calculation is epidemiological data. Therefore, a crucial assumption in the PC method is that the individual in question is adequately represented by the populations from which incidence data are drawn. This assumption may lead to some statistical and practical difficulties, which are discussed in later Sections and in Appendix 5.

An even more fundamental problem is that the question "What is the probability that the cancer was caused by exposure to radiation?" may not be correctly formulated. It presupposes that there is a single, though unknown cause. However, while radiation may have been a contributing factor, there may have been other equally important factors involved. Implicit in the PC approach is the assumption of mutual exclusivity, which asserts that one and only one factor caused the cancer (See Section 3.3). Yet current theories of carcinogenesis suggest that multiple causation is a common occurrence. For example, if a cancer is initiated by one agent, such as radiation, and then promoted by other exogenous factors over a period of years, one can legitimately view the final tumor as the result of several joint causes.

A more appropriate question would be "What share of the responsibility for this cancer can reasonably be attributed to each of the several factors that may have contributed to its development?" The answer to this question, although ideally drawing on the best available scientific knowledge, cannot be derived from factual information alone, but must also depend on trans-scientific value judgements. Questions of risk attribution among multiple causes involve questions of value as well as questions of fact, and therefore cannot be resolved through "objective" empirical arguments.

2.2 Definition of Probability of Causation

The concept of probability of causation (PC) has been advanced by several scientists [4] as a means of estimating the likelihood that an observed cancer in an individual was due to a particular radiation exposure as

opposed to other carcinogenic factors. In its simplest form, the probability of causation formula can be expressed as follows:

$$\text{Probability of causation} = \frac{\text{Risk attributable to particular radiation exposure}}{\text{Total risk due to all causes}}$$

Here, the risk attributable to radiation is defined as the expected increase over the normal cancer incidence rate when a population is exposed to the level of radiation in question.* As an example, if the normal incidence rate for leukemia in males aged 30 to 34 is 28×10^{-6} per year [10], and if the excess risk due to one additional rad of exposure were 2×10^{-6} per year, then the probability of causation due to this exposure would be $2/(28 + 2) = 6.7$ percent. This may be expressed symbolically as

$$\text{Probability of causation} = \frac{R_R}{R_R + R_N}$$

where R_R = risk attributable to the radiation exposure

R_N = risk attributable to normal incidence

$R_R + R_N$ = total annual risk of leukemia

This will be called the "simple" PC formula. The risk values in this formula (e.g., R_R) are defined in present applications of the simple PC approach as attributable risks, based on epidemiological data. That is, the R_R term represents the increased incidence rate of cancer due to

* As mentioned in Section 2.1, a key assumption made in practice is that the risks to the individual may be derived from epidemiological data for representative populations.

exposure to a single factor, relative to a baseline of zero exposure. The simple PC formula does not attempt to account for interactions among factors, although efforts have been made to generalize the formula in order to deal with such interactions [3]. This omission is important because it leads to an emphasis on single factors, drawing attention away from the question of how responsibility for a cancer can best be apportioned among the several factors that caused it.

The above expression has sometimes been said to "represent" or "approximate" the probability of causation or the "causative odds" [1,4]. While it is tempting to try to treat this ratio as a probability, such an interpretation can be sustained only under certain restrictive conditions. Section 3 and Appendices 2 and 3 discuss this point in detail, but the crux of the matter is that the mathematical form of the simple PC formula requires strong assumptions (e.g., that a cancer can result from radiation or smoking, but not both) if it is to be consistent with the laws of probability.

When an individual has been exposed to a number of mutually exclusive carcinogenic agents, each with a measurable risk, then the PC approach has a legitimate interpretation. The simple PC formula can then be extended as follows to explicitly consider these other agents:

$$PC_R = \frac{R_R}{R_R + \Sigma_j R_j}$$

Here, PC_R denotes the (conditional) probability that a particular exposure to radiation, R, caused the cancer, given that a cancer has been observed; while j ranges over all possible causes of the cancer other than the particular radiation exposure, and can include "natural" sources, air pollution, dietary factors, cigarette smoking, and sources

of radiation other than the one being singled out (e.g., medical X-rays). For example, the following formula has been proposed [4] for use in the context of the Orphan Drug Act:

$$PC_R = \frac{R_R}{R_R + R_N + R_O + R_A}$$

Here R_N represents the risk due to natural causes, R_O the risk due to other radiation exposures such as medical X-rays, and R_A the risk due to other carcinogenic agents in the environment (e.g., toxic chemicals). This mathematical form can only be justified if certain assumptions are made about the independence of the different factors, as Section 3 explains.

2.3 Potential Limitations of the PC Approach

As discussed above, an important limitation of the simple PC formula in practical applications is its apparent implicit assumption of mutually exclusive causes. The presence of multiple causative factors in producing a cancer could lead to incorrect applications of the simple PC formula. For example, factors may be co-carcinogenic (i.e., the combined effect of two or more co-occuring factors is greater than the sum of their separate effects) or promoting (i.e., one factor alone would produce little or no effect, but acting sequentially they produce a strong effect). Efforts to make the formula adequately realistic will be hindered by the present limited scientific understanding of carcinogenesis when joint causes are involved. However, even if this key limitation is set aside, there are other significant obstacles that should be recognized.

On the theoretical side, the excess cancer rate due to a particular radiation exposure is assumed to be constant among different groups exposed to various occupational or dietary factors. The attributable risk estimates used in the PC formula are not conditioned on these other factors. However, this type of independence among factors is not borne out by the available evidence. For example, two leading researchers have stated that "there is increasing recognition of the concept that the majority of human cancers result from a complex interaction between multiple environmental and host factors"[17]. In particular, the possible interaction between radiation and smoking is still a subject of scientific debate [5].

On the practical side, each term in the PC formula must be estimated for an individual from available toxicological and epidemiological data. Such risk estimation involves substantial uncertainties, due to the difficulties of exposure estimation and extrapolation of risk to low dose levels [1]. Moreover, not only must it be assumed that the individual being analyzed can be represented by statistical averages, but also the statistics for different risk factors will invariably be drawn from different studies involving separate, unmatched populations. The resulting variability can be substantial. In the SEER data, for example, the incidence rate of some cancers varies by a factor of three across different geographic sites, and data were not collected for many regions of the U.S. [10]. The BEIR report [15] clearly acknowledges the large uncertainties in risk estimates for low-LET radiation.

In many cases, adequate data for quantifying the risks from other known carcinogens (e.g., pesticides) will be not merely variable, but simply unavailable. These risk factors can be ignored, or gross assumptions can be made in order to quantify them, but in either case the numbers produced by the PC formula will be suspect. The use of upper bounds may be appropriate in setting standards for health protection, but may not be justifiable in the context of victim compensation [13]. In general,

estimates of risk using single numbers (i.e., point estimates) rather than intervals in the PC calculation are misleading, since they do not acknowledge the many uncertainties involved in developing the risk estimates. Section 4 examines these sources of uncertainty in greater detail, and Appendix 5 explores the plausible widths of confidence intervals.

It should be noted that the weaknesses of the PC approach have largely been recognized by its pioneers, who have cautioned against possible abuses in relying on it to determine eligibility for health damages compensation. For example, one investigator ([3], p. 4) points out that attributable risk "can be used to derive an average, statistical risk to the average person in a population group, but not for specific individuals unless they match the average statistical individual exactly." Another scientist, while advocating the use of the PC formula, has stressed the fact that the data requirements of the PC approach are difficult to satisfy, noting that "The input information usually is far less than adequate and fraught with dubieties"[1]. Thus, the literature shows an awareness of limitations that could make useful application of the PC approach difficult in practice. In the following Sections, each of the potential limitations identified here is explored in greater detail.

3. TECHNICAL EVALUATION OF THE PC APPROACH

3.1 Introduction

The preceding Sections have described the conceptual underpinnings of the simple PC formula and have suggested that it can be applied, at best, only under very restricted conditions. To pin down exactly what those conditions are requires a more formal analysis. This Section provides the required analysis, and identifies conditions, both necessary and sufficient, under which the simple PC formula holds.

Two necessary conditions -- "mutual exclusivity" and "additive independence" -- are identified and explained, and the consequences of violating them are examined. Although conditions that are both necessary and sufficient to justify the PC formula are difficult to find, at least one set of sufficient conditions, involving a simplistic birth-and-death model, is identified. More important, the analysis shows that the PC formula, rather than being a mathematical or statistical identity, requires some biological or epidemiological model to justify it and to provide an interpretation for its results.

The remainder of the Section examines the validity of using population averages, or "marginal" data, as estimates of cancer incidence for specific individuals drawn from the population, without conditioning on relevant individual characteristics. There is no statistical justification for this procedure in the absence of additional assumptions (e.g., that there is little or no variation in the population). Using population averages instead of individual-specific data in the PC formula could -- depending on the assumptions made about the distribution of individual characteristics and the method of sampling -- lead to PC estimates that provide little or no information about the "true" PC value for an individual.

3.2 Summary of the PC Formula

The probability of causation (PC) formula has been put forth as a scientific tool for answering the following difficult question: Given that a person has been exposed to several possible sources of cancer, and given that a cancer has developed, what is the probability that a particular one of the sources -- e.g., the first -- was the one that actually caused it? For example, if there are only two possible sources, say R and N, of a cancer C, then what is the conditional probability that C was caused by R, rather than N, given that C has occurred? The answer proposed by the simple PC formula is that

$$Pr(R|C) = \frac{R_R}{R_R + R_N} \qquad (3.1),$$

where $Pr(R|C)$ denotes the conditional probability that Factor R caused C, given that C has occurred; and R_R and R_N denote the "attributable risk" rates for Factors R and N, respectively. If there are m sources, S_1, S_2, ..., S_m, instead of only two, the the above formula is generalized to give*

$$Pr(S_i|C) = \frac{R_i}{R_1 + \ldots + R_m}, \; i = 1, 2, \ldots, m \qquad (3.1'),$$

as the so-called "probability of causation" for Factor i.

* Source i consists of the selected individual's entire history of exposure to the i^{th} possible cause of health effect E; thus, it does not simply refer to a potential causative agent, but to the individual's actual exposure to this agent [4].

The attributable risk rate R_i is usually defined as the difference in incidence rates of C between matched populations exposed and unexposed, respectively, to Factor i. Symbolically, this definition becomes

$$R_i = Pr(C|S_i) - Pr(C|\overline{S}_i),\ i = 1, 2, \ldots, m \qquad (3.2),$$

where $Pr(C|S_i)$ denotes the probability that a randomly selected member of the population that has been exposed to Factor i will have effect C; while $Pr(C|\overline{S}_i)$ denotes the probability that a randomly selected member of the population that has not been exposed to Factor i will have effect C. To make this definition unambiguous, it is necessary to assume that R_i does not depend on what other factors, in addition to S_i, are present in an individual's exposure history. This interpretation of incidence rates in terms of conditional probabilities assumes simple random sampling from a population in steady state, as illustrated in Appendix 4.

Working on behalf of the Department of Health and Human Services, an ad hoc committee of the National Institutes of Health (NIH) is currently developing radioepidemiological tables using a slight variation of the above approach. They define the probability of causation as the ratio of the attributable risk, R_i, to the total risk when factor i is present, $Pr(C|S_i)$. In the case where only one factor is being considered (e.g., radiation) in comparison to natural incidence, and no interactions are present, this formulation is equivalent to the one discussed below.

3.3 The Assumption of Mutual Exclusivity

The PC formula proposes a probabilistic answer to a specific question: which is the factor (or exposure) that is responsible for a given cancer? Before examining the mathematical basis of the proposed answer, it is useful to identify the circumstances for which the question makes sense.

To ask which factor or exposure caused a tumor, or to ask for the probability that any particular one caused it, presupposes that only one factor is to blame -- that the possible causes, in other words, are mutually exclusive.* This assumption of mutual exclusivity is implicit in the PC formula, which produces as output a list of m "probabilities of causation", one for each factor, to indicate how likely each factor alone is to have been the cause of an observed cancer. If more than one factor or exposure could have contributed to the onset of the cancer, however, then this formulation must be changed to include two components:

(i) What subset of factors contributed to the onset of the observed cancer; and

(ii) What share of responsibility for the observed cancer is properly attributable to each factor?

Instead of m possible answers to the first question, one for each possible factor, there may be as many as 2^m-1, one for each possible subset of factors [22, p. 422]. The second question cannot be answered by statistical or scientific methods alone, but requires trans-scientific judgements about how to attribute risk in the presence of joint causes. Thus, a necessary condition for the PC formula to be usable -- since it does not include the trans-scientific judgements required to answer question (ii) above -- is that the m possible causes of the observed health effect must be mutually exclusive. In other words, multiple causation through initiation and promotion, as well as other types of interactions, are implicitly ruled out by the PC formula. These concepts are amplified through a simple (although biologically unrealistic) illustration in Appendix 1.

* Mutually exclusive causes must not be confused with mutually exclusive events. The simple PC formula presupposes that causes are mutually exclusive; this does not imply that cancer-initiating events from different sources cannot be statistically independent.

3.4 Interpretation of Attributable Risk Rates

The PC ratio is formed using the attributable risk rates, R_i, defined in Equation (3.2). In order for the ratio to actually represent a probability, however, the attributable risk terms must be interpreted very carefully.

The most natural interpretation of attributable risk rate R_i is that it is the conditional probability of an individual developing a specified type of cancer, if he is exposed to source S_i alone. (Exposure level and latency period are assumed to be specified.) That is, R_i would be the probability that source S_i alone would have caused the cancer, C, given that S_i was the only source to which the individual was exposed. If C_i is used to denote the event that source i alone caused cancer C, and if S_i denotes exposure to source S_i alone, then this definition of R_i can be written symbolically as

$$R_i = Pr(C_i|S_i) \qquad (3.3),$$

Equation (3.2) says something different, namely that R_i is the increase in incidence rate brought about by exposure to S_i. Nothing is said about other factors to which the individual may have been exposed. Indeed, if Equation (3.2) is to be unambiguous, it must be assumed that the increment of incidence rate, R_i caused by a factor is independent of what other factors are present.

In fact, an even stronger implication holds. It can be shown that the simple PC formula in Equation (3.1) holds if and only if Equation (3.2) for measuring attributable risk holds, where attributable risk is defined by Equation (3.3). Moreover, under this interpretation, either is equivalent to the condition

$$Pr(C_N|R \text{ and } N) = Pr(C_N|N \text{ alone}) \qquad (3.4),$$

i.e., a necessary and sufficient condition for the simple PC formula (Equation (3.1)) and the incidence rate definition of attributable risk

(Equation (3.2)) to hold is that the probability that a particular cancer was caused by one factor must be independent of whether the other factor was present.*

In the case of m mutually exclusive causes, the above independence condition may be generalized as follows:

$$Pr(C_i|S_i) = Pr(C_i|S_i, S_j, S_k, \ldots) \qquad (3.4')$$

where the right-hand side is conditioned on any subset of the m factors that includes S_i. Algebraically, this assumption is reflected in the denominator of the PC formula. Here, the total risk from several sources is represented as the sum of the risks that would accrue from each separately, i.,e.,

$$Pr(C|S_1, S_2, \ldots, S_m) = Pr(C_1|S_2) + Pr(C_2|S_2) + \ldots + Pr(C_m|S_m) \quad (3.5).$$

This additive independence condition states that the probability of an individual developing a specified type of cancer, given that he has been exposed to sources S_1, S_2, ... S_m, is the sum of the probabilities that each source separately would cause the cancer. Combining the probabilities in this way requires that the probability of each particular source causing a cancer be totally independent of what other sources may be present. A necessary and sufficient condition for the PC formula, Equation (3.1') to be unambiguously defined is the condition of additive independence, assuming that the R_i are to be interpreted as in Equation (3.2) and (3.3). Without this assumption, it would be necessary to replace each attributable risk term, R_i, with a function, $R_i(S_1, S_2, \ldots, S_m)$, indicating how R_i depends on the exposure profile $(S_1, S_2, \ldots, S_m)$. The term R_i alone would be ambiguous, since

* In epidemiology, it is conventional to use "net" and "crude" hazard rates and probabilities in an effort to distinguish between the risk due to a factor in isolation and the risk due to it in the presence of competing causes; the latter is necessarily smaller. See reference [18] and Chapter 9 of reference [22].

it would have different values for different exposure profiles [18]. The additive independence condition is weaker than the requirement of mutual exclusivity, however, in that it is a consequence of the mathematical form of the PC formula, rather than being implicit in the very formulation of the the PC concept. The significance of the additive independence condition, and the consequences of violating it, are explored further in Appendices 2 and 3. It is shown that the condition of additive independence required by the simple PC formula is logically inconsistent with the assumption of mutual exclusivity, as long as the denominator of the PC formula is interpreted as the total probability of cancer, given exposure. For as additional factors are added to the denominator, each with non-zero attributable risk, this sum could eventually exceed one, unless joint causes were allowed.

3.5 Summary of Conditions for Use of the PC Formula

The foregoing observations do not imply that the simple PC formula could never be correct under any interpretation of its terms. For example, the "one-hit" model of cancer with competing Poisson risks as sources, developed in Appendix 1, coupled with assumptions regarding Poisson births and deaths in the population and "steady state" conditions, would be sufficient to justify Equation (3.1). The attributable risk rates, R_i, would then be interpreted not as probabilities or as differences of probabilities, but as average arrival rates for "hits" from different sources. Appendix 4 describes this model. Although these conditions and interpretations are the only sufficient ones of which we are presently aware, they are biologically implausible. A justification or derivation of Equation (3.1) from a biologically and epidemiologically realistic model has yet to be offered.

Recently it has been suggested that radiation may act independently from other carcinogens, based on observations of direct genetic responses, often in relatively simple biological organisms, to low level radiation exposure (LLRE) [21]. However, the inference that these experimental

results are relevant to estimation of the impact of LLRE in cancer induction fails to take into account the complex, multistage nature of the carcinogenic process. Indeed, there is substantial support in the experimental oncology community for the view that promotion or cocarcinogenic influences, that are not directly carcinogenic themselves, may be the key rate-limiting steps in determining whether a cancer ultimately occurs in a host, regardless of the tumor-initiating stimulus [17]. Thus, the designation of LLRE as an exclusive and independent factor in determining cancer risk does not seem to fit with our understanding of how multiple environmental and endogenous influences can affect the final outcome with respect to the actual occurrence of cancer in a human.

Although it is difficult, and perhaps not possible, to find realistic sufficient conditions under which the simple PC formula would hold, we have here identified two conditions that are necessary for it to hold: without either of them, the formula cannot be used. These conditions are:

- Mutual Exclusivity: The PC concept is not applicable to cases in which there are joint or contributing causes: it assumes that exactly one cause is fully responsible for any observed health effect.

- Factor Independence: The attributable risk rate, R_I, for factor, source, or exposure i must be independent of which other factors are present (or of the levels of the other factors); otherwise, it is not uniquely defined. Thus, no synergistic or antagonistic interactions among factors are allowed.

Any epidemiological/biological model that is proposed as justification for the PC formula must at least provide plausible rationales for these two conditions, explaining why neither joint causes nor interactions arise in the contexts where the formula is applied. What other assumptions must be made to obtain the PC formula remain to be

determined. However, it is important to note that the plausibility of the PC formula, and the credibility of its results, cannot be firmly established in the absence of an underlying model.

3.6 Problems of Application: Use of Aggregate Data

The preceding Sections have claimed that the PC formula as it is currently used is not adequately formulated, in the sense that it lacks a supporting model; that its results can only be interpreted as true "probabilities" under restrictive assumptions; and that it requires data that are generally not available. These drawbacks notwithstanding, the formula has been applied in many numerical calculations with real-world data [1-3]. How can applications be made of a formula for which the required data are not available, and how is it that the logical and interpretational difficulties with this formula have not been taken more fully into account?

The answers appear to be related. In discussing the requirement of additive independence, we assumed that the numerical values of the attributable risk rates R_1, R_2, etc., were perfectly known. (See Appendix 2). In practice, such cell-specific incidence rates, given at the level of individual factor combinations, (or "cells" of a contingency table) are not usually available. So instead, marginal incidence rates -- that is, incidence rates obtained by aggregating rates for individual cells across rows or down columns of the contingency table, and so associated with its margins -- are used. For example, we find in the literature that

> "The incidence of thyroid cancer cases for the male is approximately 3 per 10^5 persons per year...The risk of radiation-induced thyroid cancer...is about $.5/10^5$ rem/yr. Accordingly, the upper limit causative probability from the formulation above would be $0.5R/(3 + 0.5R)$, where R is the amount of radiation to the thyroid in rads or rem." [4]

(The qualifier "upper limit" refers to the fact that additional factors could presumably be included in the denominator.)

We see that in applying the PC formula, the average incidence rate for a very general class of subjects (i.e., males) is being used as a proxy for the unknown incidence rate that would describe a particular combination of factors (i.e., belonging to a particular cell of the contingency table.) Cell-specific data appropriate for a particular male individual might include information on age, race, blood type, drinking habits, dietary history, smoking history, previous exposure to medical and occupational radiation as well as to chemical carcinogens, geographic areas lived in and background levels of carcinogens and radiation in each area, and so forth. (See Section 4.1.)

Since such data are not generally available -- and since a statistical model relating incidence rates to these variables is not available anyway -- practitioners have not attempted to collect them in applying the PC model. Instead, they have selected a few variables (e.g., sex and age) and used the marginal risk rates obtained by distinguishing among individuals on the basis of these factors alone as substitutes for the cell-specific risk rates. However, the marginal incidence rates are not sufficient to determine representative cell rates, so that use of marginal (known) rates in place of cell-specific (unknown) ones may give very misleading results.

Appendix 5 shows that tabulated PC values based on population averages may not be positively correlated with "true" eligibility for compensation. Their validity as predictors of the true PC values depends on how individual responses are distributed about the population average. The use of aggregate data to determine compensation eligibility in individual cases can be justified only if one is willing to make (and defend) additional assumptions, such as that the population in question is relatively homogeneous with respect to the attributes being measured. Otherwise, application of the PC method in practical situations may imply a substantial likelihood of error in the screening of claimants.

4. SOURCES OF UNCERTAINTY IN RISK ESTIMATION

4.1 The Range of Potential Carcinogens

Application of the probability-of-causation model, as described in Section 2.2, may require that each of the important carcinogenic agents to which an individual has been exposed be identified, and that an incidence rate for each agent be estimated from population data. In this identification process, the causative agents to be considered will usually range over a host of occupational, environmental, and lifestyle factors. The sources of radiation alone are numerous, including naturally-occurring background radiation and voluntary exposure for medical reasons. The difficulty of identifying which potential causative agents were actually active in a particular case is compounded by the fact that "background" radiation and medical radiation alone are estimated to give the American public an average annual dose which is perhaps 350 times as great as the average exposure to the public and workers from the nuclear industry [16]. Trying to isolate the effects of a particular exposure to nuclear radiation would, therefore, be like looking for a needle in a haystack. In addition, there are hundreds of chemicals - both naturally-occurring and industrially-produced -- which are suspected carcinogens, yet quantitative risk data are available for only a handful of these chemicals.

While a great deal of scientific effort has been expended on quantifying the risks associated with selected carcinogenic agents, it is widely acknowledged that most human cancers cannot be attributed to environmental or occupational exposures. John Higginson, former director of the International Agency for Research on Cancer (IARC), has suggested that environmentally-caused cancers account for only a small percentage of human cancer incidence [6], and as shown in Table 4-1 other researchers have estimated their importance at less than 3%, as compared with diet and lifestyle factors (about 70%), and occupational exposures (about 5%). As evidence of this claim, Higginson cites the example of

Table 4-1: Proportions of cancer deaths attributed to various different factors [7]

Factor or class of factors	Percent of all cancer deaths: Best estimate	Range of acceptable estimates
Tobacco	30	25-40
Alcohol	3	2-4
Diet	35	10-70
Food additives	<1	-5-2*
Reproductive and sexual behaviour	7	1-13
Occupation	4	2-8
Pollution	2	<1-5
Industrial products	<1	<1-2
Medicines and medical procedures	1	0.5-3
Geophysical factors	3	2-4
Infection	10?	1-?
Unknown	?	?

*Allows for the possible protective effect of anti-oxidants and other preservatives.

U.S. Mormons, who do not smoke, drink alcohol, or consume caffeine, and have a 50% lower cancer rate than the average U.S. white population. Moreover, there is no significant difference in cancer rate between rural Mormons and those living in urban industrialized areas with higher pollution levels. Lifestyle factors also appear to outweigh hereditary causes of cancer; for instance Japanese immigrants to the U.S., after a few generations, develop the same high breast and colon cancer rates as Americans, while their stomach cancer rate declines from the typically high Japanese level.

As pointed out in Section 3.6, population averages do not reliably represent individual exposure conditions. Yet even if the laborious process of identifying all relevant potential carcinogenic agents were completed for a particular individual, it is highly unlikely that they could all be quantified for use in the PC formula. As a practical matter, it seems probable that only the identifiable and quantifiable causes of cancer can actually be included in the denominator of the PC expression. This will tend to penalize those causes that have been most extensively studied; specifically, there will be a tendency to overestimate the relative importance of ionizing radiation as compared to other causes. For example, the simple PC formula would yield a PC_R value of 100% for those age groups in which no natural incidence of a specific cancer has been observed. Yet the failure to detect a rare cancer may be a consequence of inadequate sample size, so that radiation is assigned the full burden of causation only by default.

4.2 Overview of Risk Estimation Methods

The methodology for estimating human cancer risks in a specific exposure scenario is well established, and the overall procedure is similar for both ionizing radiation and chemical carcinogens. First, the potency of the carcinogen must be quantified from the best available data. The potency is usually expressed in terms of the observed incidence rate of a specific cancer at various exposure levels, i.e., the dose-response relationship. Then the actual exposure level of the human population in

question must be estimated. Finally, information about exposure and potency must be combined to obtain an estimate of the expected cancer incidence at the particular exposure level. If actual human exposures fall well below the range at which potency data were calculated, as is frequently the case, then it is necessary to extrapolate the dose-response relationship downward using a statistical extrapolation procedure.

The primary basis of any risk estimation exercise is a data set that displays the effects of various types of exposures. Two main avenues are available for scientific risk estimation -- use of human epidemiological data and use of animal toxicological data. Unfortunately, both of these avenues have significant limitations. In the case of epidemiological data, while effects can be recognized fairly accurately, it is difficult to estimate exposures or to eliminate the confounding effects of multiple agents. In animal studies of chemical carcinogens, the situation is converse -- exposures can be carefully controlled, but it is difficult to extrapolate effects observed in the laboratory to human populations. Radiogenic risk estimates are primarily based on epidemiological data, and are generally believed to be more reliable than risk estimates for chemicals. There are only a few substances, notably asbestos and benzene, for which adequate human cancer data are available, based on occupational exposure studies.

Risk estimation remains an inexact process, relying heavily on human judgement and theoretical assumptions to derive numerical results. As a consequence, no risk estimate should be accepted without a clear understanding of the assumptions that were incorporated and the quality of the data that were utilized. There will always be significant uncertainty associated with estimates of chronic effects such as cancer, due to inherent limitations in the methodology of risk analysis. The major sources of uncertainty correspond to the three major analytic steps listed above:

- Uncertainty in the data used to estimate the potency of a carcinogenic agent, including statistical and biological issues.

- Uncertainty in the data used to estimate the exposure levels for populations or individuals in question.

- Uncertainty introduced by the modelling assumptions required to combine the potency and exposure estimates into an estimate of risk.

The following Sections describe these sources of uncertainty in greater detail, focusing first upon radiation and then upon chemical carcinogens.

4.3 Uncertainties in Risk Estimation for Ionizing Radiation

There is considerable uncertainty surrounding the true magnitude of risks associated with exposure to low-level ionizing radiation. Variations in radiogenic risk estimates by a factor of two are considered small by epidemiologists [8], yet such uncertainties can render probability of causation estimates unreliable for compensation purposes, as illustrated in Appendix 5. A number of sources of uncertainty in radiogenic risk estimation that could hinder the use of the simple PC formula have been identified including [1]:

- estimation of the radiation dose
- low-dose extrapolation
- use of population risk estimates for an individual
- categorization of the disease
- incomplete knowledge of other carcinogenic risk factors

Another extremely important uncertainty is the presence of poorly understood interactions among joint causes. Some of the important sources of uncertainty that may inhibit the development of PC estimates are discussed further below:

Exposure Estimation - The most difficult aspect of retrospective epidemiological studies is quantifying the dose rate of radiation over the time period of interest. Dosimetry will be particularly problematic for intermittent exposures, as in the case of an individual subject periodically exposed to medical and dental X-rays. Quantification of radiation dose to a particular organ is necessary in order to evaluate hypothesized causal dose-response relationships. The absorbed dose from radiation is dependent upon the type and energy of radiation, and whether the source is external or internal to the body. Dosimetry is particularly problematic when individuals are exposed to multiple radiation types of various energies from both internal and external sources. Such varied exposure is commonplace in medical procedures and occupational radiation exposures. The tolerance level associated with dosimeters used for external radiation measurements of occupational exposure may be substantial, and additional uncertainties are generated when extrapolating these external measurements to organ doses.

Geographic Variations - There are large geographic variations within the U.S. in both background radiation and cancer incidence. The baseline incidence of cancer in different locations in the U.S. often varies by a factor of 2 and for some cancers 3 or more. The main factor affecting natural incidence variation appears to be urban versus rural domicile,* but many individuals will have resided in several geographic areas with different cancer rates. These types of variations raise questions about the use of national survey data such as SEER [10] as the basis for PC estimates, since data based on limited geographical samples may not apply to individuals drawn from other populations.

* These urban-rural differences have been attributed to the confounding effects of diet and lifestyle [7], and this view is supported by the example of the Mormons mentioned earlier.

Statistical Power - When the number of observed incidents from which the underlying rate is estimated is small -- often the case in studies of cancer -- then many plausible incidence rates are consistent with these observations, making it impossible to identify a useful "best guess" value. This is true even if the sample size is large. For example, if zero cancers are observed in a sample of size 1000, it is still not implausible that the "true" incidence rate might be .002. In consequence, the incidence rates required by the PC formula cannot necessarily be estimated with enough precision to be useful: the plausible range of PC values may be too wide to support any definite conclusions. To partially offset these uncertainties, many practitioners have advocated the use of conservative or "worst-case" assumptions in estimating risk rates. This approach may be warranted in some regulatory settings but it can lead to unrealistic conclusions when applied in individual cases.

Diagnostic Bias - In epidemiological studies there may be a tendency toward misclassification of cases and controls, particularly when diagnostic criteria are not uniform and when diagnoses are made over a span of time in a variety of clinical settings. Diagnostic disputes will, of course, be especially difficult to resolve in the case of individual victims.

Temporal Factors - There are substantial variations in susceptibility to cancer for different age groups, and in the latency period from initial exposure to expression of the cancer. Over time, an individual will be exposed to other carcinogens, and may also develop other illnesses. In addition, the relationships between radiation dose rate and total dose in producing carcinogenic effects are not clearly understood.

Population Variability - Unlike laboratory animals, individual humans display great variability in both their lifestyle characteristics and their susceptibility to disease. For example, some cigarette smokers live a normal or greater-than-normal life span without suffering from any

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of the diseases commonly associated with smoking. Conversely, lung cancer may occur in persons who never smoke and who are not exposed to other carcinogens to an unusual degree. Perhaps the largest population variable is the wide human genetic pool. For a disease like cancer in which the basic genetic constitution plays such a prominent role, individual clusters of genetic uniqueness seem to be the overriding factor; for example, breast cancer has a strong genetic component. A whole host of other genetic disorders are associated with increased cancer risk, even among heterozygotes where the disorder is only carried by the host, but is not evident. In addition, there are wide genetically-based variations among humans with respect to their ability to metabolize foreign chemicals. For these reasons, epidemiological data representing broad population averages will often fail to be adequately representative of individuals with particular genetic makeups. This is to some degree demonstrated in the SEER data [10], where the incidence of some cancers as a function of race varies by a factor of 3 or more.

Dose-Response Estimation - One of the greatest sources of uncertainty in radiogenic cancer risk estimation is the use of dose-response models to extrapolate the effects of low-LET radiation at low doses, as acknowledged by the BEIR Committee [15, p. 2]. Critical review of the BEIR Report is a continuing process [20], and future revisions will no doubt have substantially different interpretations of the epidemiological data base. The BEIR decision to use a linear-quadratic model represents a compromise between other, more extreme models, but additional research on low-dose effects is needed. The BEIR estimates of cancer risk are generally regarded as conservative, in the sense that they overstate the true risk. However, the NIH ad hoc committee is proposing to use a linear dose-response model, which is even more conservative.

4.4 Uncertainties in Risk Estimation for Chemical Carcinogens

Although the PC formula is intended for application to radiation injuries, rather than to injuries caused by chemicals or other

carcinogens, the formula may nonetheless require in its denominator estimation of attributable risk rates for chemicals. Yet the state-of-the-art for risk assessment of chemical carcinogens is considerably less advanced than for radiation. The scientific limitations in this field were recently summarized by Lester Lave, a well-known risk analysis expert:

> "No-one should underestimate the difficulties and uncertainties of quantitative risk assessment, ... [which] provides controversial, generally ambiguous results. At best, much uncertainty will surround the quantitative estimates of risk. The risk assessment is of little use unless attention is given to the sources of uncertainty and the effects each has on the resulting estimates" [9, p. 11]

Some of the important sources of uncertainty for chemical risk estimation are discussed below:

Threshold Controversy - One important point of controversy in risk extrapolation is the existence of a threshold level for carcinogenic response to a chemical substance. Some argue that an organism is able to cope with low doses of a substance through metabolic processes or repair mechanisms, so that harmful effects do not appear until a certain minimum threshold, or "safe dose", is surpassed. Others contend that a carcinogenic substance must be considered potentially harmful at any dose, and that even a single molecule may initiate a tumor at the cellular level; this is the so-called "one-hit" hypothesis. Unfortunately, due to realistic restrictions on sample size in animal experiments, it is extremely difficult to statistically confirm or reject the no-threshold hypothesis. Even with no observed tumors, the upper statistical confidence bound on the true risk will be linear at low doses, no matter what model is assumed [11]. Thus, the threshold issue may never be satisfactorily resolved through purely statistical arguments.

Selection of Dose-Response Model - A number of alternate models are available which accept either laboratory or epidemiological data as input and calculate a dose-response relationship based on certain assumptions

about the form of the curve. The most widely accepted dose-response model at the present time is the multi-stage model, which has great flexibility in curve-fitting, and also has a physiological justification. The two most widely used models, until recently, were the "one-hit" model and the log-probit model, which represent opposite extremes in terms of shape -- the former has a linear shape, whereas the latter has a steep threshold-like curvature. In numerous applications with different substances it has been found that these three models span a broad range of risk estimates at typical human exposure levels.

Interspecies Dose Conversion - In order to extrapolate laboratory animal results to humans, an interspecies dose conversion must be performed. Animals such as rodents have different sizes, intake rates and lifespans from humans, and therefore are expected to respond differently to a specific dose level of a chemical. Estimation of equivalent human doses is usually performed by scaling laboratory doses according to observable species differences. Unfortunately, detailed quantitative data on the comparative pharmacokinetics of animals and humans are practically nonexistent, so that scaling methods remain approximate. There is about an order-of-magnitude difference in risk estimates between the two most commonly-used dose conversion methods; namely, surface-area ratios and body weight ratios. Additional uncertainties arise when the route of dose administration (e.g., intramuscular injection) does not correspond to the expected route of human exposure (e.g., inhalation, ingestion, or skin absorption).

Species Specificity - The most questionable assumption in risk extrapolation is that a substance which is carcinogenic in laboratory animals is also a human carcinogen. In fact, species differences in susceptibility are frequently observed; the most famous instance of a false negative animal study was the case of thalidomide (a teratogen), which produced human birth defects although it had no effect on rodents. Conversely, the assumption of carcinogenicity to humans may be false, even though the substance in question is a proven carcinogen in several

animal species. In such a case, the lower bound on the excess risk to humans is effectively zero, in the sense that zero-risk is a possibility which cannot be dismissed.

By choosing an appropriate set of data and making certain dose conversion assumptions, it is possible to apply various dose-response models that estimate response at low doses [12]. Each model postulates a different shape of dose-response curve in extrapolating from high to low doses. By using several models, a range of uncertainty can be established between the least conservative and the most conservative results. The resulting range of uncertainty will frequently span several orders of magnitude, as illustrated in Table 4-2 for the case of saccharin. Thus, in most cases, it will be scientifically impossible to select a "best estimate" within the broad uncertainty range described above.

4.5 Implications of Uncertainty

The implication of the foregoing comments is that the risk rates R_R, R_N, etc., required by the PC formula are not well-determined. Moreover, uncertainty in estimating such rates is magnified when their ratio is formed, making it even more difficult to interpret or compare the "probability of causation" numbers produced by the formula. The PC formula requires empirical knowledge that is not available, and attempts to use it without such knowledge can lead to answers that may be very misleading, as shown in Appendix 5.

In summary, even if the restrictive conditions described in Section 3 are met, application of the PC formula will often be prevented by inability to quantify the contributions of individual risk factors, especially those in the denominator. Applications of the formula in individual cases may entail long and costly debates over the data and assumptions to be used, particularly as regards which populations (if any) are representative of the individual in question, and what relevant factors are to be considered.

TABLE 4-2

ESTIMATED HUMAN CANCER RISKS FROM A DAILY DOSE RATE OF 0.12g OF SACCHARIN EXPRESSED IN LIFETIME CASES PER MILLION EXPOSED

Method of Extrapolation to Low-dose	Method of Rat/Human Extrapolation		
	Surface Area Rule	mg/kg/day Human Equivalence	mg/kg/lifetime Human Equivalence
Single-hit	1200	210	5.20
Multi-stage	5	-	-
Multi-hit	0.001	0.001	0.001
Log-probit	450	21	4.2

Source: Saccharin: Technical Assessment of Risks and Benefits, National Academy of Sciences, Washington, D.C.

5. SUMMARY AND DISCUSSION

5.1 Principal Conclusions

The problem of assigning a "probability of causation" to one of several possible carcinogenic agents in individual cases of radiation exposure has been critically examined, with the following principal results.

- The simple PC formula that has been proposed for computing probability of causation requires a biological and epidemiological model to justify and support it. The credibility of the formula cannot be assessed without such a model. The formula satisfies the axioms of probability only under very restrictive assumptions, such as mutual exclusivity, that will be violated in many practical situations and that any proposed model would have to explain.

- Alternative possible PC formulas that do not require mutual exclusivity would have to include one or more "risk accounting" axioms for apportioning responsibility among joint causes, in order to satisfactorily meet the needs of decision-makers concerned with setting compensation policy. These additional axioms would necessarily have to incorporate "trans-scientific" human value judgments, rather than factual scientific knowledge alone.

- If the formula is applied in its existing form, there will be a number of significant sources of uncertainty associated with estimating each of the attributable risk terms. As a result, the confidence interval surrounding the PC estimate will tend to be extremely broad, making it difficult or impossible to legitimately draw useful, reliable, or credible conclusions.

- Even if the available data were to permit the precise estimation of a PC value, it is not possible to correctly portray the interactions among risk factors using the existing formula. However, modification of the formula to adequately account for these interactions would require data that are not presently available.

We conclude that the use of a formula will, in general, not provide reliable measures of risk attribution in individual cases. It is possible that risk accounting methods could be used to assign probable shares of causation among joint causes, overcoming some of the restrictions inherent in the probabilistic approach. No matter what approach is used, however, the problems of uncertainty in risk estimation and the lack of adequate data -- especially in going from population averages to individual cases -- will remain as inherent limitations. Rather than developing standardized tables, it might be more useful to develop a systematic process of dealing with multiple causation on a case-by-case basis.

5.2 Trans-Scientific Issues

Proposals to use the PC approach as a basis for awarding compensation raise concerns that go beyond truly scientific issues, and that relate to the policy questions raised in Section 1. How adequate is the simple PC formula as a basis for awarding compensation? Does it include all the right elements, or most of them? We believe that it does not.

The simple PC formula is a purely technical formula, taking as input the estimated doses and risk factors from exposures to different carcinogens and radiation. But determining eligibility for compensation is a social process, and, to be acceptable in such a context must consider not only the physical factors of exposure, but also the social significance of such facts. Some of the important questions that might normally be considered in assessing responsibility for compensation are:

- Was the claimant aware beforehand of the cancer risks to which he was being exposed? Was he adequately warned?

- Were some or all of the risks accepted voluntarily (as would often be the case for cigarette smokers) so that part of the cause of an individual's cancer plausibly consisted of his own actions?

- Were the risks voluntarily assumed, with full knowledge of potential consequences, in return for an increased salary or payment? Was a premium already included in the routine compensation paid to the claimant?

- Are the risks known with sufficient precision, confidence, and credibility to allow a useful assignment of responsibility? Were they known (identified, quantified, etc.) at the time that they were incurred? Were the probable hazardous consequences of the risky activity recognized by the parties involved?

Depending on the answers to questions such as these, there may be entirely different ethical obligations to pay compensation in situations with identical physical facts. For example, one of the "factors" that should probably be included in a determination of compensation liability for a claimant's cancer would be the presence of the claimant in proximity to a radiation source, and the proportion of blame for a cancer assigned to this factor would presumably depend on whether such proximity was voluntary on the part of the claimant, despite the presence of adequate warnings. A second factor would be the degree to which the risks were recognized at the time they were incurred, as well as the credibility of current retrospective assessments of the effects of different risk factors. Suppose, for example, that a paramount goal of the tort system were defined as one of increasing incentives to take appropriate care to prevent injury. The credibility and precision of scientific risk estimates associated with hazarous activities in a

particular case would seem critical in determining whether shifting the loss to a third party would successfully increase the due care incentive, or whether it would simply impose a crushing liability for something that could not have been foreseen.

These types of considerations are at present not included in the PC formulation, which is being applied only to physical factors, without regard for the social and ethical questions of who should be considered responsible for those factors. Yet criteria of intention, knowledge, and foreseeability are usually considered key determinants of moral and legal liability. Moreover, even the implicit decision of which factors (e.g., background radiation) are to be considered as potential "causes" of cancer, and which factors (e.g., gender or cigarette smoking) are not, embodies unstated and perhaps subconscious policy decisions that cannot be made on a "purely scientific" basis.

It has sometimes been argued that while the PC formula is admittedly imperfect, it is nonetheless the best that contemporary science has to offer as a guide to compensation liability. Even if this were true, the question remains whether the "best available" formula is "good enough" to actually be useful or acceptable in practice. Without dealing in subjective value judgements, it is, of course, impossible to say whether use of the simple PC formula as currently envisioned is "acceptable." But it would be illuminating for potential users of the formula to state some minimal set of normative criteria for "acceptability", and then to check how well the formula performed in terms of these criteria. It would seem too soon to accept the formula for practical use until at least a preliminary evaluation of its performance (relative, say, to that of a lottery) has been made.

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APPENDIX 1

Mutual Exclusivity and the "K Hits" Model

In this appendix, the role of mutual exclusivity (Section 3.3) is clarified through a simple example, and the consequences of violating it are examined. No pretense is made of biological realism: the focus is entirely on clarifying the conceptual content of the simple PC formula.

Suppose that a worker has been exposed to only two sources of cancer: occupational radiation, R, and nonoccupational (background) radiation, N. For simplicity, assume that the mechanism of cancer induction is such that each source delivers "hits" to the worker's cells according to a random (Poisson) process, with average arrival rates (or "intensities") of λ_R and λ_N, respectively; the worker develops cancer as soon as a cell receives K hits. Given that a worker is observed to have a cancer, what is the probability that source R, his occupational exposure, caused it?

If one examines this question, the problem of attribution becomes apparent. Suppose that some of the K hits came from source R and that the rest came from source N: how shall we say which source "caused" the cancer? Both caused it. Asking for the probability that either one alone caused it is misguided: there is a nonstatistical question regarding policy toward attribution that must be answered first. To apply the PC formula, one must assume that this type of situation does not arise.

If the number of hits contributed by each source is unknown, then it is possible to ask for the probability that source R alone contributed <u>all</u> the hits, and is thus strictly responsible for the cancer, given that K hits have been received, i.e., that a cancer has occurred. This "probability of causation" turns out to be simply

$$\Pr(R|C) = \left(\frac{\lambda_R}{\lambda_R + \lambda_N}\right)^K \qquad (1)$$

This reduces to the PC formula, Equation (3.1), if and only if: (i) the average arrival rates, λ_R and λ_N, are proportional to the attributable risk rates R_R and R_N defined in Equation (3.2); and (ii) K=1, so that the problem of joint causes cannot arise.

Although the "K hits" model is admittedly simplistic, it demonstrates that the PC formula is not necessarily valid. It is not a universal statistical truth or theorem, but rather the result of biological assumptions. Successful use of the formula requires a "one-hit only" assumption of the above type, to assure that the observed cancer results from exactly one source, rather than from a sequence of contributing causes (e.g., initiators, promoters, etc.). The PC formulation is only as credible as the biological model used to support such an assumption.

Much more sophisticated one-hit and multi-hit models of carcinogenesis, which take into account some aspects of the dynamics of biological responses to "hits", and which allow for hit "density" in tumor initiation, are available in the literature; see, e.g., Reference [22], Section 15.4. The fundamental points made here for the simplest model also hold for more elaborate ones.

APPENDIX 2

An Example Involving Additive Independence

The role of additive independence in the simple PC formula may be clarified by examining how the formula becomes ambiguous without it. Consider the simple hypothetical example in Table A-1. There are only two factors: smoking and radiation.

The incidence rate of cancer in nonsmokers is (for simplicity of exposition) assumed to be 10% for those who have been exposed to radiation and 0% for those who have not; among smokers, the corresponding numbers are 40% and 20%, respectively. Therefore $R_1 = .1$ is the risk posed by exposure to Factor 1 (radiation) alone, while $R_2 = .2$ is the risk from exposure to Factor 2 (smoking) alone. Factor independence as defined in Equation (3.4') is violated, since the increase in incidence rate brought about by smoking depends on the presence or absence of radiation exposure.

Note that the concept of "attributable risk" as a difference in incidence rates between exposed and unexposed populations is ambiguous in this example. In Table A-1, we have taken the attributable risk for radiation to be $R_1 = .1$, since this is the increase in incidence rate between a population exposed to neither carcinogenic factor and a population exposed to radiation alone. However, it would seem at least as valid to compute the attributable risk as $R_1 = (.4 - .2) = .2$, the increase in incidence rate brought about by exposure to radiation among smokers, since the PC calculation is made only for individuals who have been exposed to both factors (i.e., for individuals from the lower right-hand cell). Similarly, R_2 could be computed as $(.4 - .1) = .3$ instead of .2. In short, calculation of "the" attributable risk due to a factor

Factor 2	Factor 1: No Radiation	Factor 1: Radiation
No Smoke	0	.1
Smoke	.2	.4

Table A-1: Risk Rates for Different Combinations of Two Nonadditive Risk Factors.

depends on what other factors are present in the combination of factors to which the individual in question was exposed, unless additive independence holds.*

Not surprisingly, the probabilities of causation computed for each factor depend on which attributable risk values are used. Using $(R_1, R_2) = (.1, .2)$ gives a PC for radiation of

$$PC_1 = Pr(C_1|C) = \frac{.1}{.1 + .2} = 1/3.$$

This implies that $PC_2 = 2/3$.

Using $(R_1, R_2) = (.2, .3)$ gives

$$PC_1 = \frac{.2}{.3 + .2} = 2/5.$$

Either value seems equally valid (or invalid); they would coincide if and only if additive independence held. Thus, the condition of additive independence is necessary not only to make the PC definition unambiguous, but also to make it a reasonable expression for probability of causation.

Note that the values of $Pr(C_1|C) = 1/3$ and $Pr(C_2|C) = 2/3$, were computed from the attributable risk values of .1 and .2 in the upper right and lower left cells of Table A-1, respectively, and so are independent of the incidence rate (namely .4) in the lower right-hand cell. This seems counter-intuitive. For example, if the incidence rate

* This is the distinction between "net" and "crude" probabilities drawn in Reference [18]'s analysis of competing risks.

among those exposed to both factors had turned out to be the same as the incidence rate among those exposed to Factor 1 alone (namely .1 instead of .4 in the present example), then it might seem plausible to assign Factor 2 a zero attributable risk, and hence a zero probability of causation. Of course, smoking and radiation don't really interact in this way, but the PC calculations pay no attention to how (or whether) they do interact: the incidence rate in the lower right-hand cell -- the only cell of interest -- is completely ignored. This is justified if and only if it can be deduced from knowledge of the incidence rates in the other three cells, which again leads back to the additive independence condition.

Finally, additive independence is needed to justify the definition of probability of causation in terms of conditional probabilities of cancer given exposure (Equations (3.2) and (3.3)). The probability of getting cancer, given exposure to a source, is identical with the probability that that source caused the cancer only when no other sources that could have caused the cancer are present. Additive independence asserts that this probability remains unchanged when other factors are introduced.

APPENDIX 3

Implications of Additive Independence

This appendix demonstrates a logical difficulty associated with the additive independence condition.

Equation (3.5) can be rewritten, using Equation (3.3), as

$$\Pr(C|S_1, S_2, \ldots, S_m) = R_1 + R_2 + \ldots + R_m \qquad (1)$$

This is the denominator of the simple PC formula as it is commonly interpreted [3]: it says that the probability that a cancer C will occur can be represented as the sum, taken over all factors, of the probabilities that it will be caused by each factor alone. But this interpretation leads to a logical contradiction: the probability that any one factor alone causes cancer must be reduced when competing risks are introduced [18, 22].

To see why, it is useful to explicitly show the role of time. Instead of having R_i denote the probability that a cancer would be caused by exposure to Source i (either alone or in conjunction with other sources), let $R_i(t)$ denote the probability that source i would cause a cancer by time t, given exposure to all m factors. Similarly, let R(t) denote the probability that a cancer has been caused by time t. Then Equation (1) can be written, showing the role of time, as

$$R(t) = R_1(t) + R_2(t) + \ldots + R_m(t) \qquad (1')$$

But from elementary probability theory, the probability of a cancer by time t, given that the causes act independently, is

$$R(t) = 1 - \prod_{i=1}^{m} [1 - R_i(t)] \qquad (2)$$

It is easy to verify that the right-hand sides of Equations (1') and (2) cannot be equal. If the $R_i(t)$ are all sufficiently small, they may be approximately equal, but if any of the $R_i(t)$ approaches one as t increases, then the equality is clearly violated. Thus, the assumption of additive independence leads to an inconsistency if the sum $R_1 + R_2 + \ldots + R_m$ is interpreted as the probability that a cancer will occur, i.e., as the "total risk" produced by all m sources.*

The difficulty here lies not with the additive form per se: under the fundamental assumption of mutually exclusive causes, probabilities must combine additively as in Equation (1'). This follows directly from the axioms of probability theory. Inconsistency arises only when it is assumed (as per Equation (3.4)) that the risk value for any factor does not depend on what other factors are present. The ratios of the risk values for different factors may remain unchanged when additional factors are introduced, but their magnitudes must decrease [18].

In summary, the condition of additive independence, which is necessary for the PC formula to be unambiguous, is inconsistent with the interpretation of the formula's denominator as the total probability that a randomly selected individual will have cancer. This inconsistency can be overcome if the mutual exclusivity assumption is dropped, but only at the expense of introducing the additional complications described in Section 3.2.

* See Reference [18], Equation (10), for a derivation of the correct relation between $Pr(C_1|S_i$ alone) and $Pr(C_1|S_1, \ldots, S_m)$, in the context of a simple competing-risks model.

APPENDIX 4

A Markov Model Interpretation of the PC Formula

Suppose that each individual in a population can be classified as belonging to one of four states of health: healthy (H); afflicted with radiation-induced cancer (R); afflicted with nonradiation-induced cancer (N); or deceased (D). Let transitions among states occur in a "purely random" fashion, with mean rates λ_{HR}, λ_{HN}, λ_{HD}, λ_{RD}, λ_{ND}, where λ_{ij} denotes the mean transition rate for an individual from state i to state j. Let H, R, N, and D also denote the numbers of people in the corresponding states in long-run, "steady-state" equilibrium. Equilibrium requires that

$$\begin{bmatrix} (\lambda_{HR} + \lambda_{HD} + \lambda_{HN}) & 0 & 0 \\ \lambda_{HR} & -\lambda_{RD} & 0 \\ \lambda_{HN} & 0 & -\lambda_{ND} \end{bmatrix} \begin{bmatrix} H \\ R \\ N \end{bmatrix} = \begin{bmatrix} B \\ 0 \\ 0 \end{bmatrix}, \quad \text{or}$$

$$\begin{bmatrix} H \\ R \\ N \end{bmatrix} = \frac{1}{\lambda_{HR} + \lambda_{HD} + \lambda_{HN}} \begin{bmatrix} 1 & 0 & 0 \\ \lambda_{HR}/\lambda_{RD} & 0 & 0 \\ \lambda_{HN}/\lambda_{ND} & 0 & 0 \end{bmatrix} \begin{bmatrix} B \\ 0 \\ 0 \end{bmatrix},$$

where B is the birth rate. Hence, the probability that a randomly selected individual with cancer will have had his cancer caused by radiation becomes

$$\Pr(C_R|C) = \Pr(C_R|RUN) = \frac{R}{R+N} = \frac{\lambda_{HR}/\lambda_{RD}}{\lambda_{HR}/\lambda_{RD} + \lambda_{HN}/\lambda_{ND}} = \frac{\lambda_{HR}\,\lambda_{ND}}{\lambda_{HR}\,\lambda_{ND} + \lambda_{HN}\,\lambda_{RD}}.$$

Assuming that death rates from radiation-induced and nonradiation-induced cancers are identical ($\lambda_{RD} = \lambda_{ND}$), this reduces to the simple PC formula, i.e.,

$$Pr(C_R|C) = \frac{\lambda_{HR}}{\lambda_{HR} + \lambda_{HN}}$$

Note that

$$\frac{(\lambda_{HR} + \lambda_{HN})H}{H} - \frac{\lambda_{HN} H}{H} = \lambda_{HR}$$

defines the attributable risk for radiation.

The above model is sufficient to justify the simple PC formula, but involves biologically unrealistic assumptions, e.g., that likelihood of getting cancer is independent of age. Further analysis of competing risk models may be found in References [18] and [19].

APPENDIX 5

Implications of the Use of Aggregate Data

Applying population averages to individual cases for the purposes of determining individual-specific probabilities of causation violates sound statistical practice and common sense. In highly variable populations, averages may be representative of no one; in any individual case, case-specific information provides insights and exceptions that are likely to make overall statistical patterns for the population at large irrelevant to or inadequate for the specific case in hand. Nonetheless, it may be useful to see why aggregate "marginal" data, averaged over rows or columns in the "contingency table" summarizing the distribution of population characteristics, does not provide an adequate substitute for cell-specific data conditioned on individual combinations of characteristics.

Table A-2 presents an example. In both Table A-2a and Table A-2b, the marginal incidence rates and sample sizes are the same. If all we know about a claimant is that he smokes, then the maximum likelihood estimate (MLE) of the incidence rate is 5/14. Similarly, what is known about him can be used to determine corresponding marginal risk rates for him according to the following table:

What is Known	Marginal Risk Rate
• Smokes	5/14 = .36
• Does not smoke	1/6 = .17
• Has been exposed to radiation	1/3 = .33
• Has not been exposed to radiation	1/4 = .25
• No information as to exposure	3/10 = .30

	No Radiation	Radiation	
No Smoke	1/10	4/20	5/30 = $\frac{1}{6}$
Smoke	9/30	16/40	25/70 = $\frac{5}{14}$
	10/40	20/60	

Table A-2a

	No Radiation	Radiation	
No Smoke	5/10	0/20	5/30 = $\frac{1}{6}$
Smoke	5/30	20/40	$\frac{25}{70}$ = $\frac{5}{14}$
	10/40	20/60	

Table A-2b

Table A-2: Known Marginal Incidence Rates Do Not Determine Cell-Specific Rates.

These numbers are the same for both tables, even though the cell-specific incidence rates are very different. Table A-2b has been constructed to show how extremely misleading marginal data can be. The "background" incidence rate of 5/10 = 50% is five times the corresponding rate in Table A-2a, and the interaction between smoking and radiation is much stronger. The rate of 1/6 for nonsmokers is not representative either of the 50% incidence rate among those who have not been exposed to radiation, nor of the 0% rate among those who have. Of course, this is an unrealistic example, contrived for dramatic effect; nonetheless, the main point is clear: knowledge of marginal incidence rates tells very little about the incidence rates in individual cells. Knowing that smokers have an average incidence rate of 5/14 and that those exposed to radiation have an average incidence rate of 1/3 tells nothing about the average incidence rate among those exposed to smoking and radiation, it could as well be 16/40 = .4 or 20/40 = .5. But individuals belong to specific cells, and are exposed to the specific incidence rates therein: it is therefore generally inappropriate to apply marginal, or average, data to individual cases. This problem is known in the literature as the problem of nonidentifiability [19].

To see why it is generally undesirable to apply response data based on population averages to individuals drawn from the population, it is useful to examine the confidence bands and error rates that might plausibly result from doing so. Of course, these in turn depend on the biological model used and the epidemiological assumptions made concerning population variability, and there is insufficient knowledge at present to uniquely specify a correct model or set of assumptions. However, an initial idea of the plausible confidence and error magnitudes involved can be derived from some simple calculations.

Suppose that an individual is exposed to two Poisson competing risks, providing "hits" with intensitites λ_1 and λ_2. Each source represents a different factor, and different individuals respond differently to hits from different factors, reflecting variations in susceptibility.

Specifically, assume that the conditional probability that a randomly selected individual will develop cancer, given that he receives a hit from source i, is a random variable p_i, depending both on the individual and the source of the hit (i.e., the responsible factor) and uniformly distributed between 0 and some (presumably very small) number, α_i. Thus, p_i indicates the individual's susceptibility to effects from Factor i, and is drawn at random from the interval $[0, \alpha_i]$.

In this simple model, the average attributable risk from Source i is $1/2\ \alpha_i\ \lambda_i$, and the average PC value for this source is

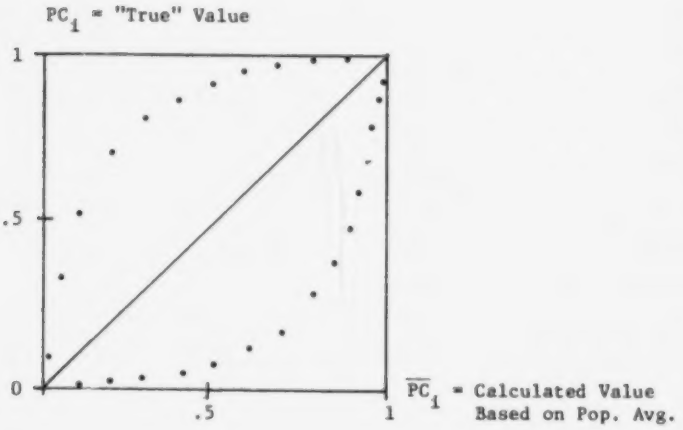
$$\overline{PC}_i = \frac{1/2\ \alpha_i\ \lambda_i}{1/2\ \alpha_1\ \lambda_1 + 1/2\ \alpha_2\ \lambda_2}$$

Thus, the PC value for an individual depends on his (unknown) susceptibilities to different factors, and is uniformly distributed about this midpoint.

Suppose we use $\overline{PC}_i$ as a proxy for PC_i. What is the relationship between these two variables? Figure A-1 presents an answer in terms of 90% confidence bands: <u>given</u> an estimated $\overline{PC}_i$ of 51%, for example, there is a 90% confidence that the "true" PC_i is between 9% and 92%. Similarly, the 90% confidence band for a $\overline{PC}_i$ of 10% is $1\% \leq PC_i \leq 53\%$. Thus $\overline{PC}_i$ provides only a very weak estimate of PC_i: the confidence bands are so wide that firm conclusions are hard to draw, and compensation decisions based on the $\overline{PC}_i$ estimates are quite likely to be in error.

Figure A-2 quantifies the error probabilities for the decision rule that compensates an individual if and only if the estimated PC value exceeds 10%. If $\overline{PC}_i = 30\%$, for example, then there is about a 13% chance that the true PC_i is less than 10%. This error probability for false compensation increases for smaller values of $\overline{PC}_i$, and decreases for larger ones. As $\overline{PC}_i$ approaches 10%, the probability of falsely compensating (or falsely failing to compensate) a victim approaches 50%. This general pattern holds for nearly any reasonable distribution of p_i values in the population. Thus, for example, if 100 people are selected

FIGURE A-1: 90% Confidence Bands for "True" PC Given Calculated PC



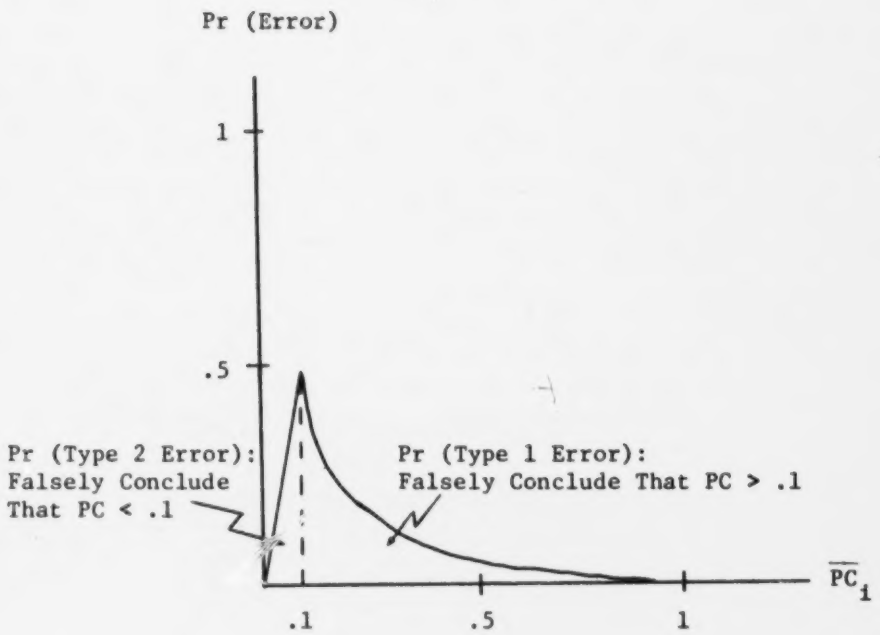
Method of Calculation:

$$\frac{\overline{PC}_i}{10 - 9\,\overline{PC}_i} \leq PC_i \leq \frac{10\,\overline{PC}_i}{9\,\overline{PC}_i + 1}$$

Assumptions:

- p_1 and p_2 for an individual are uniformly distributed
- "1-hit" model (possibly with binomial censoring)

FIGURE A-2: Analysis of Error Rates for 10% Compensation Threshold



Method of Calculation:

$$\Pr(\text{Type 1 Error} \mid \overline{PC}_i > .1) = \frac{1 - \overline{PC}_i}{18\ \overline{PC}_i}$$

$$\Pr(\text{Type 2 Error} \mid \overline{PC}_i < .1) = \frac{9\ \overline{PC}_i}{2 - 2\ \overline{PC}_i}$$

Assumptions:

- p_1 and p_2 for an individual are uniformly distributed
- "1-hit" model with binomial censoring

from a population of claimants as being eligible for compensation, based on their having a PC value slightly exceeding 10%, then about 50 of them will be incorrectly chosen. Of course, even among those that are correctly chosen, only about 5 will have cancers caused by the factor in question (e.g., radiation), according to the PC model.

It is instructive to contrast this situation with the one commonly encountered in insurance, where individual policies are legitimately based on group statistics. This is legitimate in insurance because the net return (premiums minus claims payments) to the insurance company is the sum of individual net returns over all policies. As the number of individuals increases, the average return per individual (i.e., the sample mean) converges to the population average with probability 1, and the sample variance (approximately equal to individual variance divided by number of individuals) approaches zero. For any particular individual (n=1), however, this is not the case: there is no summation of independent random variables, and thus, no convergence of individual to population values. Thus, the PC formula's application of epidemiological data to individuals is very different from an insurance company's calculation of average group rates from group statistics. In the latter case the Central Limit Theorem acts to ensure that sample and expected averages converge; in the former, no averaging is present.

Although population averages are not perfect substitutes for individual-specific measurements, it seems reasonable to suppose that they provide at least some useful information -- that they are better than nothing. For example, suppose that "average" probabilities of causation could be tabulated for various population groups (e.g., female smokers, male nonsmokers, etc.) for a particular cancer-inducing factor, such as radiation. Given that we wish to compensate all persons with a PC of .5 or more (for example), can the average PC numbers help guide our compensation decisions? For example, can we at least say that it is always preferable to compensate individuals with higher average PC's (i.e., belonging to groups with higher average PC's) than with lower ones?

Unfortunately, the answer is, unequivocally, No: there is no necessary monotonic relation between average PC and probability of being eligible for compensation.

A simple example illustrates the point. Consider two groups: A and B. Suppose for simplicity that the true PC values (i.e., the values that would be calculated based on complete individual information) are uniformly distributed between 0 and .8 among the members of Group A, and that they are uniformly distributed between .4 and .55 among the members of Group B. The "average" PC numbers tabulated for the two groups would thus be 1/2 (0 + .8) = 40% for Group A, and 1/2(.4 + .55) = 47.5% for Group B. Now suppose that we had to choose whether to award a dollar of compensation to a randomly selected member of Group A or to a randomly selected member of Group B. Based on average PC values alone, the Group B member would seem to be the obvious choice. Yet the probability that the individual's true PC exceeds 50% (our assumed ideal compensation criterion) is (.8 - .5)/(.8) = .375 for a member of Group A, and only (.55 - .5)/(.55 - .4) = .05/.15 = .333 for a member of Group B. Thus, the individual with the lower tabulated PC value is, in this case, the one who is more likely to deserve compensation.

The above example is simplistic and extreme, based on deliberately chosen distributional assumptions, but can easily be adapted to reflect different underlying PC distributions and compensation criteria, although not always with such extreme results. The important point is that unless something is known about the distribution of "true" PC values for individuals, there is no reason to believe that the PC values calculated from population averages in any way represent an index of "probable eligibility" for compensation. Treating tabulated average PC values as though they were individual-specific PC values has no a priori statistical justification in the absence of specific and defensible distributional assumptions, and could lead to a misallocation of compensation resources.

The CHAIRMAN. With that, we will recess this committee until further notice. We intend to hold further hearings on this after we get these materials through, and we hope these further hearings will help us get further down the road that we want to go.

Thank you so much.

[Whereupon, at 12:15 p.m., the committee recessed, to reconvene at the call of the Chair.]

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